2. Labor or Capital

With respect to employment of labor or capital, Complainants rely on investments by Cercacor in research and development for the rainbow® sensors. CIB at 309.[131] Complainants claim that "Cercacor has employed the [redacted] to work on rainbow®." CIB at 299 (citing CDX-0015C.015 (summarizing CX-0633C)). As such, Complainants assert that Cercacor's expenditures in the employment of R&D labor or capital for the rainbow® sensors amounts to [redacted] pre-2018 and [redacted] from 2018-Q1 2021. *Id.* at 309 (citing CX-0633C at "R&D Spend History" tab; CX-0644C). In addition, Complainants state that "Cercacor has performed the [redacted] of its R&D on rainbow®, accounting for [redacted] in R&D through July of 2021." *Id.* at 310 (citing Tr. (Hammarth) at 524:25-525:5).

Apple argues that Complainants offer no corroborating documentation for these R&D expenses or explain how their calculation provides a reliable basis for allocations necessary for the economic prong requirement. RIB at 276. In addition, Apple contends that Complainants fail to show that the R&D projects identified in Cercacor's R&D expenditures are exclusively related to the rainbow® sensors, rather than to non-domestic industry products and projects. *Id.* For example, Apple asserts that Complainants' expenditures include Ember, a commercialized product sold by Cercacor that is not a domestic industry product. *Id.* (citing Tr. (Hammarth) at 532:5-13). Similarly, Apple claims that Mr. Hammarth also identified [redacted] as a [redacted]

[131] Complainants also set forth other labor or capital expenditures for the rainbow® sensors. *See* CIB at 309-10. However, because the other expenditures appear to be less reliable and are not as closely tied to Complainants' asserted bases for significance, only Cercacor's employment of R&D labor or capital is addressed herein.

[redacted] as an [redacted]; and [redacted] as related, in part, to Ember. *Id.* (citing RX-1201C at 81:21-83:5; Tr. (Hammarth) at 527:12-528:22). Apple argues that Complainants allocate costs associated with each of these products and projects to the rainbow® sensors without any allocation for the non-domestic industry Ember product or any explanation for including R&D on [redacted] in the absence of any showing that any of the rainbow® sensors use that technology. *Id.* at 276-77.

Contrary to Apple's assertions, the undersigned finds that a preponderance of the evidence demonstrates that these R&D expenditures are reliable. According to Mr. Kiani, the chairman and CEO of Masimo and Cercacor, Cercacor developed the rainbow® technology. Tr. (Kiani) at 94:8-17. Apple does not dispute this. Mr. Jeroen Hammarth, the CFO of Cercacor, testified that for the purposes of this investigation, Cercacor exported records from its ERP system and used Excel records from various tax analysis that it had performed over the years in the normal course of business. Tr. (Hammarth) at 523:22-524:2. He also testified that he prepared a financial spreadsheet showing Cercacor's R&D spend.[132] *Id.* at 524:3-13; *see also* CX-0633C.[133] Mr. Hammarth testified that Cercacor's total R&D on the rainbow sensors though Q1 of 2021 was over [redacted]. Tr. (Hammarth) at 525:3-5. This is consistent with the data in

[132] The undersigned finds that such evidence is reasonable under the circumstances of this investigation. As the Commission has stated, "there is no need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (May 16, 2008) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.")

[133] Apple refers to exhibit CX-0633C and states that it "concerns Cercacor R&D Labor, with no apparent relevance." RRB at 163. Sworn testimony demonstrates that Cercacor developed the rainbow® technology, making Cercacor's investment in R&D labor related to rainbow®, *i.e.*, the subject of CX-0633C, relevant. *See* Tr. (Kiani) at 94:8-17, 119:9-12; Tr. (Hammarth) at 524:3-13.

the financial spreadsheet prepared by Mr. Hammarth, as well as the financial spreadsheet prepared to support Mr. Young's declaration to the complaint.[134] *See* CX-0633C; CX-0644C at Tab "Rainbow Chart" (showing that Cercacor's rainbow® R&D spend from 2007-2020 is about [redacted]); Tr. (Young) at 488:2-17. And according to Mr. Hammarth all of that R&D "was done in the U.S." Tr. (Hammarth) at 525:6-8.

Moreover, the undersigned disagrees with Apple that certain R&D projects need to be excluded from Cercacor's R&D expenditures. The undersigned finds that a preponderance of the evidence shows that Cercacor specifically allocated certain of its projects to the rainbow® sensors. *See, e.g.*, CX-0633 at Tab "Summary Calc" (showing subtotals for rainbow vs. non-rainbow). For example, Apple claims that the [redacted] project is outside the scope of the rainbow® sensors. However, Mr. Hammarth testified that the [redacted] and the rainbow® sensor measures a collection of nonvital signs, including [redacted].[135] *See* Tr. (Hammarth) at 528:1-6; *see also id.* at 528:23-529:2. Similarly, Mr. Hammarth testified that Ember is a Cercacor product that "incorporates our technologies for hemoglobin measurement, carbon monoxide measurement, and some others."[136] Tr. (Hammarth) at 532:5-13; *see also* RX-1201C at 25:10-17 ("Ember is a small device that measures a number of blood constituents noninvasively."). The evidence, including documents

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[134] As with the Masimo Watch, Complainants prepared several financial spreadsheets detailing their domestic expenditures for the rainbow® sensors. *See* CIB at 299-300. While Apple argues that these spreadsheets are unreliable as to the rainbow® sensors, Apple's arguments are unpersuasive for the same reasons as discussed above with respect to the Masimo Watch. *See* Part VII.C. *supra*.

[135] The [redacted] *See* RX-1201C (Hammarth Dep.) at 82:2-4.

[136] [redacted] is the internal project name for the Ember product. *See* RX-1201C (Hammarth Dep.) at 82:8-10.

and sworn testimony, therefore shows that Cercacor accurately allocated certain R&D projects as related to the rainbow® sensors.

The evidence demonstrates that Cercacor's R&D investments in the rainbow® sensors are quantitatively and qualitatively significant.

Cercacor's largest project has been the rainbow® technology. For example, from 2005-2020, Cercacor spent a total net R&D expense of about [redacted], with about [redacted] of that dedicated to rainbow® technology. Tr. (Hammarth) at 524:16-525:5; CDX-0008C.002 (summarizing CX-0633C); CX-0633C. Moreover, as previously discussed, [redacted] of the investment in rainbow® technology was incurred in the U.S. Tr. (Hammarth) at 525:6-8; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [DI products] occurs in the United States."), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by* Comm'n Notice, EDIS Doc. ID 762554 (Feb. 4, 2022). Other than criticizing Complainants' other quantitative comparisons, or arguing that Complainants' expenditures are overstated and unreliable, Apple does not specifically rebut Complainants' contention that Cercacor's R&D investments are quantitatively

significant.[137] *See, e.g.* RIB at 278; RRB at 174-75. The evidence therefore demonstrates that Cercacor's domestic investments in R&D labor for rainbow® are quantitatively significant.

Cercacor's domestic R&D investments for the rainbow® sensors are also qualitatively significant. Cercacor's R&D effort related to the rainbow technology has been a large part of its business, and again, was incurred entirely in the U.S. *See, e.g., Certain Percussive Massage Devices*, Inv. No. 337-TA-1206, Comm'n Op. at 10-15, EDIS Doc. ID 759545 (Jan. 4, 2022) (affirming finding that complainant satisfied the economic prong of the domestic industry requirement and finding qualitative significance, in part, because complainant's domestic industry products "would not exist without [its] domestic operations and spending" because it "designed and developed the DI Products in the United States"). In addition, not only has it been Cercacor's largest project in terms of R&D spend, as explained above, but over the years, Cercacor has employed the [redacted] of its employees to work on rainbow®. *See* CDX-0015C.015 (summarizing CX-0633C) (showing that Cercacor has dedicated between [redacted] and [redacted] of its employees to rainbow®); CX-0633C. In addition to Cercacor's domestic R&D labor investments, Masimo has also made domestic investments in R&D labor for rainbow®. *See* Tr. (Young) at 499:15-500:7; CX-0644C. Lastly, it is worth noting that Masimo also manufactures important components of the rainbow® sensors, semiconductor LEDs and optical packages of emitters and detectors, at its Hudson, New Hampshire facility in the U.S., distinguishing Complainants from a mere importer. *See* Tr. (Young) at 507:7-15; *see also* CX-0636C; CX-0638C; *see Certain Toner Supply Containers and Components Thereof (II)*, Inv. No. 337-TA-1260, Comm'n Op. at 11-12, EDIS Doc. ID 777011 (Aug. 3, 2022) (finding qualitative

[137] Apple's arguments disputing quantitative significance focus on Complainant's cost of goods (COGS) analysis. *See* RIB at 278. The undersigned, however, is not relying on that analysis in finding quantitative significance.

significance where a domestic industry is based on "core manufacturing activities," affirming an initial determination finding that "[s]uch activities have long been recognized as a domestic industry within the meaning of section 337.").

In opposition, Apple argues that "Complainants ignore that rainbow® product revenues generally comprise only [redacted] of Masimo's total product revenues in 2020." *See* RIB at 278. Apple, however, fails to explain why this would be a more appropriate comparison under these circumstances. *See, e.g.*, *Certain Carburetors and Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 28 (Oct. 28, 2019) ("Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.").

Accordingly, the undersigned finds that Complainants have demonstrated significant employment of labor or capital with respect to the rainbow® sensors. As discussed above, however, Complainants have not satisfied the domestic industry requirement with respect to the '127 patent because the current rainbow® sensors have not been shown to practice any claim of the '127 patent.

IX. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is the undersigned's final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of claims 24 and 30 of the '648 patent. There has been no violation of the statute with respect to the asserted claims of the '501 patent, the '502 patent, the '745 patent, or the '127 patent.

This determination is based on the following conclusions of law:

1. The Commission has subject matter jurisdiction over this investigation.

2. The Accused Products have been imported into the United States, sold for importation, and/or sold within the United States after importation.

3. The Commission has *in rem* jurisdiction over the Accused Products.

4. The Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.

5. The technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.

6. Claim 12 of the '501 patent, claim 28 of the '502 patent, and claim 12 of the '648 patent are invalid.

7. The '501 patent, '502 patent, and '648 patent have not been shown to be unenforceable.

8. The economic prong of the domestic industry requirement has been satisfied with respect to the '501 patent, the '502 patent, and the '648 patent.

9. The Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent.

10. The technical prong of the domestic industry requirement has been satisfied for claim 18 of the '745 patent.

11. Claims 9, 18, and 27 of the '745 patent have not been shown to be invalid.

12. The '745 patent has not been shown to be unenforceable.

13. The economic prong of the domestic industry requirement has been satisfied with respect to the '745 patent.

14. The Accused Products have not been shown to infringe claim 9 of the '127 patent.

15. The technical prong of the domestic industry requirement has been satisfied for claim 9 of the '127 patent.

16. Claim 9 of the '127 patent has not been shown to be invalid.

17. The economic prong of the domestic industry requirement has not been satisfied with respect to the '127 patent.

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the complaint and exhibits thereto, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(h)(2), this initial determination shall become the determination of the Commission 60 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44. 19 C.F.R. § 210.42(h)(2).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.[138] The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.

Monica Bhattacharyya
Administrative Law Judge

[138] Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF **Inv. No. 337-TA-1276**

Certificate of Service – Page 1

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Katherine M. Hiner, hereby certify that the attached **INITIAL DETERMINATION** has been served upon the following parties as indicated, on **January 24, 2023**.

Katherine M. Hiner, Acting Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Masimo Corporation and Cercacor Laboratories, Inc.:

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On Behalf of Respondent Apple Inc.:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1276**

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by respondent Apple, Inc. of Cupertino, California ("Respondent") of certain light-based physiological measurement devices and components thereof (as defined in paragraph 2 below) that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 ("Asserted Patents").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of infringing light-based physiological measurement devices and components thereof manufactured by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the

bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the entered value of the articles subject to this Order.

Accordingly, the Commission hereby **ORDERS** that:

1. Light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 and are manufactured abroad by, or on behalf of, or imported by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license from, or with the permission of, the patent owner or as provided by law; and except for parts necessary to service and repair covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), and except for covered products that are replacements for covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), provided that replacement is pursuant to a warranty for the replaced article.

2. The light-based physiological measurement devices and components thereof subject to this exclusion order (*i.e.*, "covered articles") are as follows: wearable electronic devices with light-based pulse oximetry functionality and components thereof.

3. Notwithstanding paragraph 1 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of zero percent (0%, *i.e.*, no bond) of their entered value, pursuant to subsection (j) of section 337 (19 U.S.C.

§ 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the receipt of this Order. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection ("CBP"), in advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

5. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

7. The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP.

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1276**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT Apple, Inc. of Cupertino, California cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain light-based physiological measurement devices and components thereof (as defined in Definition (G) below) that infringe one or more of claim 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 ("Asserted Patents") in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, California.

(C) "Respondent" shall mean Apple, Inc. of Cupertino, California.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648. The light-based physiological measurement devices and components thereof subject to this order are as follows: wearable electronic devices with light-based pulse oximetry functionality and components thereof. Covered products shall not include articles for which a provision of law or license avoids liability for infringement.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of covered products.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

(A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct;

(B) such specific conduct is related to the importation or sale of covered products by or for the United States; or

(C) such specific conduct is limited to importation, sale, and provision of parts necessary to repair covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), or limited to importation and provision of covered products that are replacements for covered products purchased by consumers prior to the date this Order becomes final

within the meaning of 19 U.S.C. § 1337(j)(4), provided that replacement is pursuant to a warranty for the replaced article.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2023. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the investigation number ("Inv. No. 337-TA-1276") in a prominent place on the cover pages and/or the first page. *See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf. Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the

original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

VII.
Service of Cease and Desist Order

The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 C.F.R. §§ 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting

of a bond in the amount of zero percent (0%, *i.e.*, no bond) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered products imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1276**

NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER AND A CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue: (1) a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof covered by certain claims of U.S. Patent Nos. 10,912,502 or 10,945,648 that are manufactured by or on behalf of, or imported by or on behalf of, respondent Apple, Inc. ("Apple") or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns; and (2) a cease and desist order ("CDO") directed against Apple and any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at https://www.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 18, 2021, based on a complaint filed on behalf of Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, CA (collectively, "Complainants"). 86 FR 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for

importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,912,501 ("the '501 patent"); U.S. Patent No. 10,912,502 ("the '502 patent"); U.S. Patent No. 10,945,648 ("the '648 patent"); U.S. Patent No. 10,687,745 ("the '745 patent"); and U.S. Patent No. 7,761,127 ("the '127 patent"). *Id*. The amended complaint further alleged that an industry in the United States exists and/or is in the process of being established as required by section 337. *Id*. The notice of investigation named Apple of Cupertino, California as the sole respondent. *Id*. at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *Id*.

Complainants previously withdrew certain asserted claims pursuant to Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm'n Notice (Apr. 12, 2022), and Order No. 33 (May 20, 2022), *unreviewed* by Comm'n Notice (June 10, 2022). Only claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, claims 9, 18, and 27 of the '745 patent, and claim 9 of the '127 patent remain in the investigation. Claim 18 of the '745 patent is still at issue for purposes of the domestic industry only.

On January 10, 2023, the presiding administrative law judge ("ALJ") issued the final initial determination ("Final ID"), which found that Apple violated section 337 as to claims 24 and 30 of the '648 patent, but not as to claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, claim 12 of the '648 patent, claims 9 and 27 of the '745 patent, and claim 9 of the '127 patent. *See* Final ID at 335–36. On January 24, 2023, the ALJ issued a Recommended Determination on remedy and bonding ("RD") should a violation be found in the above-captioned investigation. The RD recommended that, if the Commission finds a violation, it should issue an LEO directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a CDO directed to Apple. RD at 2, 5. The RD additionally recommended that the Commission set a zero percent (0%) bond (*i.e*., no bond) during the sixty-day period of Presidential review. *Id*. at 6. In its notice instituting this investigation, the Commission did not instruct the ALJ to make findings and recommendations concerning the public interest. *See* 86 FR at 46275–76.

On January 23, 2023, Complainants and Apple each filed a petition for review. On January 31, 2023, Complainants and Apple each filed responses to the other party's petitions.

On February 23, 2023, the parties filed their public interest statements pursuant to 19 CFR 210.50(a)(4). The Commission received numerous comments on the public interest from non-parties.

On May 15, 2023, after considering the parties' petitions and responses thereto, the Commission determined to review the Final ID in part. *See* 88 FR 32243, 32243–46 (May 19, 2023). In particular, the Commission determined to review the following findings of the Final ID:

(1) the domestic industry with regard to the ’501 patent, the ’502 patent, the ’648 patent, and the ’745 patent;

(2) obviousness with regard to the ’501 patent, the ’502 patent, the ’648 patent, and the ’745 patent;

(3) written description with regard to claim 28 of the ’502 patent and claim 12 of the ’648 patent;

(4) claim construction and infringement with regard to the ’745 patent; and

(5) subject matter jurisdiction.

Id. The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *See id*.

On June 5, 2023, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding, and on June 12, 2023, the parties filed their reply submissions. The Commission also received numerous comments on the public interest from non-parties.

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission affirms with modifications the Final ID’s domestic industry findings (both economic and technical prong) as to the ’501, ’502, ’648, and ’745 patents. The Commission additionally affirms with modifications the Final ID’s conclusion that the asserted claims of the ’501 patent are obvious, but the asserted claims of the ’502, ’648, and ’745 patents are not obvious. The Commission has determined to reverse the Final ID’s finding that Apple proved by clear and convincing evidence that claim 28 of the ’502 patent and claim 12 of the ’648 patent are invalid for lack of written description. Furthermore, the Commission affirms the Final ID’s claim construction related to the recited term “first shape” and the related conclusion that the Accused Products do not satisfy elements [1B] and [20B] of the ’745 patent. The Commission additionally vacates the Final ID’s finding that the Commission has subject matter jurisdiction over the investigation and instead finds that the Commission has statutory authority over the investigation. The Commission affirms the remainder of the Final ID that is not inconsistent with the Commission’s opinion issued concurrently herewith. As a result, the Commission finds that Apple has violated section 337 as to claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent.

The Commission has determined that the appropriate form of relief is an LEO prohibiting (1) the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof manufactured by or on behalf of Apple or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. The Commission has also determined to issue a CDO against Apple. The Commission has determined to include an exemption to the remedial orders for service or repair

or, under warranty terms, replacement of products purchased prior to the end of the period of Presidential review.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (f)(1) (19 U.S.C. 1337(d)(l), (f)(1)) do not preclude issuance of the above-referenced remedial orders. Additionally, the Commission has determined to impose a bond of zero (0%) (*i.e.*, no bond) of entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)). This investigation is terminated.

The Commission vote for this determination took place on October 26, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF	**Investigation No. 337-TA-1276**

COMMISSION OPINION

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I. INTRODUCTION

On May 15, 2023, the Commission determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on January 10, 2023. 88 Fed. Reg. 32243 (May 19, 2023). On review, the Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to U.S. Patent Nos. 10,945,648 ("the '648 patent") and 10,912,502 ("the '502 patent"), but not with respect to U.S. Patent Nos. 10,912,501 ("the '501 patent"), 10,687,745 ("the '745 patent"), and 7,761,127 ("the '127 patent"). This opinion sets forth the Commission's reasoning in support of that determination.

II. BACKGROUND

A. Procedural History

The Commission instituted this investigation on August 18, 2021, based on an amended and supplemented complaint ("Complaint") filed by complainants Masimo Corporation ("Masimo") and Cercacor Laboratories, Inc. ("Cercacor," collectively, "Complainants").[1, 2, 3] 86 Fed. Reg. 46275–76 (Aug. 18, 2021). The Complaint alleged violations of section 337 of the

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[1] The original public complaint was filed on June 30, 2021. *See* EDIS Doc. ID 745713 (June 30, 2021). On July 7, 2021, Complainants filed an "Amendment to the Public Complaint, with Amended Exhibit 2 and Appendix C." *See* EDIS Doc. ID 746186. And on July 12, 2021, Complainants filed a "Confidential Amendment to the Public Complaint and Exhibits." *See* EDIS Doc. ID 746514. The Commission has determined that the filing date of the Complaint is July 12, 2021. *See, e.g.*, 86 Fed. Reg. at 46275; Final ID at 84 (including n.24).

[2] Supplement to the Confidential Amended Complaint and Exhibits, EDIS Doc. ID 747244 (July 19, 2021); Supplement to the Amended Public Complaint and Exhibits, EDIS Doc. ID 747240 (July 19, 2021).

[3] Masimo is the owner of the '501 patent (JX-0001), '502 patent (JX-0002), '648 patent (JX-0003), and '745 patent (JX-0009). Compl. at ¶ 4. Cercacor is the owner of the '127 patent (JX-0007). *Id*. Masimo and Cercacor have rights to each of the Asserted Patents through a cross-licensing agreement. *Id.* at ¶¶ 4, 77; CX-1612C.

Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of the '501 patent; the '502 patent; the '648 patent; the '745 patent; and the '127 patent (collectively, the "Asserted Patents"). *Id*. The Complaint further alleged that an industry in the United States exists and/or is in the process of being established. *Id*. The notice of investigation named Apple Inc. of Cupertino, California as the sole respondent ("Apple"). *Id.* at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *See id.*

Prior to the issuance of the Final ID, the investigation terminated as to several claims. Order No. 25 (Mar. 23, 2022), *unreviewed by* Comm'n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed by* Comm'n Notice (June 10, 2022). At the time of the hearing on June 6–10, 2022, only the following claims remained at issue: claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, claims 9, 18,[4] and 27 of the '745 patent, and claim 9 of the '127 patent.

[4] Complainants proceeded at the hearing as to claim 18 of the '745 patent for domestic industry purposes only. *See, e.g.*, Final ID at 176. In other words, Complainants did not allege that Apple violated section 337 by infringing that claim.

On May 13, 2022, Complainants and Apple filed their pre-hearing briefs.[5] The parties filed initial post-hearing briefs on June 27, 2022,[6] and the parties filed post-hearing reply briefs on July 11, 2022.[7]

On January 10, 2023, the ALJ issued the Final ID,[8] which found that Apple violated section 337 as to only claims 24 and 30 of the '648 patent. *See* Final ID at 335–36. The Final ID found that Complainants did not establish a violation as to the other remaining asserted claims. *E.g.*, *id.*

On January 24, 2023, the ALJ issued the Recommended Determination on Remedy and Bonding ("RD").[9] The RD recommended that, if the Commission finds a violation, it should

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[5] Complainants' Pre-Hearing Brief, EDIS Doc. ID 770786 (May 13, 2022) ("CPreHBr."); Respondent Apple Inc.'s Pre-Hearing Brief, EDIS Doc. ID 770790 (May 13, 2022). On May 16, 2022, Apple filed a corrected pre-hearing brief. Respondent Apple Inc.'s Corrected Pre-Hearing Brief, EDIS Doc. ID 770874 (May 16, 2022) ("RPreHBr.").

[6] Complainants' Initial Post-Hearing Brief, EDIS Doc. ID 774000 (June 27, 2022); Respondent Apple Inc.'s Post-Hearing Brief, EDIS Doc. ID 774025 (June 27, 2022). On July 14, 2022, Complainant filed a corrected opening post-hearing brief. Complainants' Corrected Initial Post-Hearing Brief, EDIS Doc. ID 775422 (July 14, 2022) ("CPHBr."). On September 2, 2022, Apple filed a second corrected opening post-hearing brief. Respondent Apple Inc.'s Second Corrected Post-Hearing Brief, EDIS Doc. ID 779376 (Sept. 2, 2022) ("RPHBr.").

[7] Complainants' Reply Post-Hearing Brief, EDIS Doc. ID 775058 (July 11, 2022) ("CPHBr. (Reply)"); Respondent Apple Inc.'s Reply Post-Hearing Brief, EDIS Doc. ID 775073 (July 11, 2022). On September 2, 2022, Apple filed a corrected post-hearing reply brief. Respondent Apple Inc.'s Corrected Post-Hearing Reply Brief, EDIS Doc. ID 779379 (Sept. 2, 2022) ("RPHBr. (Reply)").

[8] Final Initial Determination on Violation of Section 337, EDIS Doc. ID 787653 (Jan. 10, 2023); *see also* Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789795 (Feb. 7, 2023) (Public Version).

[9] Recommended Determination on Remedy and Bonding, EDIS Doc. ID 788506 (Jan. 24, 2023); *see also* Recommended Determination on Remedy and Bonding, EDIS Doc. ID 790079 (Feb. 10, 2023) (Public Version).

issue a limited exclusion order ("LEO") directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a cease and desist order ("CDO") directed to Apple. *See* RD at 2–5. The RD additionally recommended that the Commission set a 0% bond (*i.e.*, no bond) during the sixty-day period of Presidential review. *See id.* at 6–7. The Commission's notice of investigation did not instruct the ALJ to make findings and recommendations concerning the public interest. *See* 86 Fed. Reg. at 46275–76.

On January 23, 2023, Complainants and Apple each filed a petition for review of the Final ID.[10] On January 31, 2023, Complainants and Apple each filed responses to the other respective petition.[11]

On January 24 and 30, 2023, (after the Final ID issued and petitions for review were filed), the United States Patent and Trademark Office ("USPTO") denied Apple's request for the institution of *inter partes* review proceedings ("IPRs") as to the '501, '502, and '648 patents based on a combination of references that included the same primary reference as one of the

[10] Complainants' Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 788456 (Jan. 23, 2023) ("CPet."); Complainants' Summary of Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 788457 (Jan. 23, 2023); Respondent Apple Inc.'s Petition for Review of the Initial Determination of Violation of Section 337, EDIS Doc. ID 788470 (Jan. 23, 2023) ("RPet."); Respondent Apple Inc.'s Summary of Petition for Review of the Initial Determination of Violation of Section 337, EDIS Doc. ID 788474 (Jan. 23, 2023).

[11] Complainants' Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789044 (Jan. 31, 2023) ("CResp."); Complainants' Summary of Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789045 (Jan. 31, 2023); Respondent Apple Inc.'s Response to Complainants' Petition for Review, EDIS Doc. ID 789061 (Jan. 31, 2023) ("RResp."); Respondent Apple Inc.'s Summary of Its Response to Complainants' Petition for Review, EDIS Doc. ID 789067 (Jan. 31, 2023).

combinations of references asserted against the asserted claims of those patents in this investigation. *See Apple Inc. v. Masimo Corp.*, IPR2022-01272 (USPTO Jan. 24, 2023) ('501 patent) (available at CResp. at Appx. B); *Apple Inc. v. Masimo Corp.*, IPR2022-01274 (USPTO Jan. 24, 2023) ('502 patent) (available at CResp. at Appx. C); *Apple Inc. v. Masimo Corp.*, IPR2022-01276 (USPTO Jan. 30, 2023)) ('648 patent) (available at CResp. at Appx. A).

On February 23, 2023, the parties filed their public interest statements pursuant to 19 C.F.R. § 210.50(a)(4).[12] The Commission received numerous comments on the public interest from non-parties, discussed below in the public interest section of this Opinion.

On May 15, 2023, after considering the parties' petitions and responses thereto, the Commission determined to review the Final ID in part. *See* 88 Fed. Reg. at 32243–46. In particular, the Commission determined to review: (1) the domestic industry with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent; (2) obviousness with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent; (3) written description with regard to claim 28 of the '502 patent and claim 12 of the '648 patent; (4) claim construction and infringement with regard to the '745 patent; and (5) subject matter jurisdiction. *Id.* at 32244. The Commission determined not to review the remaining findings of the Final ID, including the finding of no violation as to the '127 patent. *Id.* The Commission requested briefing on certain issues under review and also on remedy, the public interest, and bonding. *See id.* at 32244-46. The Commission's public interest briefing request also solicited input from non-parties. *See id*.

[12] Complainants' Statement on the Public Interest, EDIS Doc. ID 791050 (Feb. 23, 2023) ("CStmt."); Respondent Apple Inc.'s Public Interest Statement, EDIS Doc. ID 791062 (Feb. 23, 2023) ("RStmt.").

On June 5, 2023, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding,[13] and on June 12, 2023, the parties filed their reply submissions.[14] The Commission additionally received numerous comments on the public interest from non-parties, which are discussed below in the public interest section of this Opinion.

B. The Asserted Patents

The technology at issue in this investigation relates to user-worn devices for noninvasively measuring physiological parameters of a user.

1. U.S. Patent Nos. 10,912,501; 10,912,502; and 10,945,648: The "Poeze Patents"

The '501 patent (JX-0001), '502 patent (JX-0002), and '648 patent (JX-0003) share a common specification, claiming priority to an application filed on July 3, 2008. These patents are titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User" and name as inventors Jeroen Poeze, *et al*. These patents are referred to herein as the "Poeze patents."

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[13] Complainants' Submission in Response to the Commission's May 15, 2023 Notice of Commission Determination to Review in Part, EDIS Doc ID 797853 (June 5, 2023) ("CBr."); Respondent Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 797870 (June 5, 2023) ("RBr.").

[14] Complainants' Reply to Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 798353 (June 12, 2023) ("CBr. (Reply)"); Respondent Apple Inc.'s Reply to Complainants' Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 798383 (June 12, 2023) ("RBr. (Reply)").

Complainants assert claim 12 of the '501 patent, which depends from claim 1. *See* CPHBr. at 53-66. Claim 12 is reproduced below in a claim/element identifier chaii that includes the element designations used by the pa1iies and the Final ID.

U.S. Patent No. 10,912,501	
Identifier	**Claim/Element**
Claim 12	
[1PRE]	A user-worn device configured to noninvasively measure a physiological pai·ameter of a user, the user-worn device comprising:
[1A]	at least three light emitting diodes (LEDs);
[1B]	at least three photodiodes aiTanged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;
[1C]	a protrusion aiTanged over the interior surface, the protrnsion comprising a convex surface and
[1D]	a plurality of openings extending through the protrusion and positioned over the three photodiodes,
[1E]	the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and
[1F]	one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.
[12]	The user-worn device of Claim 1, wherein the convex surface of the protrusion is an oute1most surface configured to contact the tissue of the user and confo1m the tissue into a concave shape.

Complainants also asse1i claim 22 of the '502 patent, which depends from claims 19, 20, and 21, and claim 28, a sepai·ate independent claim. *See* CPHBr. at 66-77. These claims are reproduced below.

U.S. Patent No. 10,912,502	
Identifier	**Claim/Element**
Claim 22	
[19PRE]	A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:
[19A]	a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
[19B]	four photodiodes ananged within the user-worn device and configured to receive light after at least a po1iion of the light has been attenuated by tissue of the user;
[19C]	a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
[19D]	optically transparent material within each of the openings; and
[19E]	one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.
[20]	The user-worn device of claim 19 further comprising a thennistor.
[21]	The user-worn device of claim 20, wherein the one or more processors are fuiiher configured to receive a temperature signal from the thennistor and adjust operation of the user-worn device responsive to the temperature signal.
[22]	The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

U.S. Patent No. 10,912,502	
Identifier	**Claim/Element**
Claim 28	
[28PRE]	A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:
[28A]	a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
[28B]	a second set of LEDs spaced apa1t from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
[28C]	four photodiodes ananged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a po1tion of the light has been attenuated by tissue of the user;
[28D]	a thermistor configured to provide a temperature signal;
[28E]	a protrusion ananged above the interior smface, the protr11sion comprising: a convex surface;
[28F]	a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and
[28G]	a plurality of u-ansmissive windows, each of the tr·ansmissive windows extending across a different one of the openings;
[28H]	at least one opaque wall extending between the interior surface and the protr11sion, wherein at least the interior surface, the opaque wall and the protr11sion fonn cavities, wherein the photodiodes are ananged on the interior surface within the cavities;
[281]	one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors fmther configured to receive the temperature signal;
[28J]	a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electr·onic network;
[28K]	a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;
[28L]	a storage device configured to at least temporarily store at least the measurement; and
[28M]	a su-ap configured to position the user-worn device on the user.

Complainants further assert claim 12 of the '648 patent, which depends from claim 8, and claims 24 and 30, which depend from claim 20. *See* CPHBr. at 77-83. These claims are reproduced below.

U.S. Patent No. 10,945,648	
Identifier	**Claim/Element**
Claim 12	
[8PRE]	A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
[SA]	a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
[8B]	a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
[SC]	four photodiodes;
[8D]	a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
[SE]	a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
[SF]	a separate optically transparent window extending across each of the openings;
[8G]	one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
[SH]	a housing; and
[81]	a strap configured to position the housing proximate tissue of the user when the device is worn.
[12]	The user-worn device of Claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

U.S. Patent No. 10,945,648	
Identifier	**Claim/Element**
Claims 24 and 30	
[20PRE]	A user-worn device configured to non-invasively dete1mine measurements of a user's tissue, the user-worn device comprising:
[20A]	a plurality of light emitting diodes (LEDs);
[20B]	at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being airnnged to capture light at different quadrants of tissue of a user;
[20C]	a protrusion comprising a convex surface and
[20D]	a plurality of through holes, each through hole including a window and manged over a different one of the at least four photodiodes; and
[20E]	one or more processors configured to receive one or more signals from at least one of the photodiodes and detennine measurements of oxygen saturation of the user.
[24]	The user-worn device of Claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.
[30]	The user-worn device of Claim 20, wherein the protrusion further comprises one or more chainfered edges.

2. U.S. Patent No. 10,687,745

The '745 patent (JX-0009) is titled "Physiological Monitoring Devices, Systems, and Methods," claims priority to an application filed on June 28, 2016, and names Ammar Al-Ali as the sole inventor. Complainants asse1i that Apple infringes claims 9 and 27, and they rely on claim 18 for domestic industry purposes only. Claim 9 is reproduced below as representative of the asse1ied claims of the '745 patent.

U.S. Patent No. 10,687,745	
Identifier	**Claim/Element**
Claim 9	
[1PRE]	A physiological monitoring device comprising:
[1A]	a plurality of light-emitting diodes configured to emit light in a first shape;
[1B]	a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;
[1C]	a plurality of photodiodes configured to detect at least a po1iion of the light after the at least the po1iion of the light passes through the tissue, the plurality of photodiodes finiher configured to output at least one signal responsive to the detected light;
[1D]	a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a po1iion of light reflected from the tissue to pass through the surface;
[1E]	a light block configured to prevent at least a po1iion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue;
[1F]	and a processor configured to receive and process the outputted at least one signal and detennine a physiological parameter of the user responsive to the outputted at least one signal.
[9]	The physiological monito1ing device of claim 1, wherein the physiological parameter comprises oxygen saturation.

3. U.S. Patent No. 7,761,127

The '127 patent (JX-0007) is titled "Multiple Wavelength Sensor Substrate," issued from an application filed on March 1, 2006, and names as inventors Ammar Al-Ali, *et al.* Complainants asse1i claim 9 of the '127 patent, which depends from claim 7.

C. The Accused Products

Complainants accuse certain Apple Watches of infringing the Asse1ied Patents, including the Apple Watch Series 6, the Apple Watch Series 7, and ce1iain prototype Apple Watch

products with project names [redacted] (collectively, the "Accused Products"). CPHBr. at 37–39. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. *See* Joint Stipulation of Facts at ¶¶ 11–13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7–8. Notably, the parties do not dispute that the currently-existing Apple Watch Series SE does not infringe the Asserted Patents because it is not equipped to measure the blood oxygen saturation of a user.

D. The Domestic Industry Products

With respect to the '501, '502, '648, and '745 patents, Complainants rely on their "Masimo Watch" products. CPHBr. at 26–35. These Masimo Watch products include certain prototypes identified as the "Circle Sensor" (CPX-0021C), the "Wings Sensor" (CPX-0029C), the "RevA Sensor" (CPX-0052C), the "RevD Sensor" (CPX-0058C), the "RevE Sensors" (CPX-0019C, CPX-0020C, CPX-0065C) (collectively, the "Masimo Watch Prototypes"), and a product identified as the "W1 Watch" (CPX-0146C). CPHBr. at 30–35. The Masimo Watch Prototypes were developed as part of an iterative design process that resulted in the W1 Watch, which was not completed until after the Complaint was filed. *Id.* at 62 n.16, 18.

With respect to the '127 patent, Complainants rely on certain of Masimo's "Rainbow® Sensors." *Id.* at 36.

III. COMMISSION REVIEW OF THE FINAL ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines & Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 4 (May 1, 2015). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9–10 (July 1997) (quoting *Certain Acid-Washed*

Denim Garments & Accessories, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). With respect to the issues under review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS OF THE ISSUES UNDER REVIEW

The Commission's findings, conclusions, and supporting analysis follow. The Commission affirms and adopts the ID's findings, conclusions, and supporting analysis that are not inconsistent with the Commission's opinion.

A. Subject Matter Jurisdiction

The Final ID found that the Commission has "subject matter jurisdiction over this investigation." Final ID at 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission vacates the Final ID's "subject matter jurisdiction" finding and instead finds that the Commission has statutory authority, rather than subject matter jurisdiction, over the present investigation. *See Certain Video Security Equipment & Sys., Related Software, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-1281, Comm'n Op. at 9–10 (Apr. 19, 2023). The Commission and ALJs have used the term "jurisdiction" in the past as a shorthand for statutory authority. Executive agencies, of course, do not have jurisdiction, but rather are creatures of statute that cannot exceed their statutory authority.

B. Obviousness of the Asserted Claims of the '501 Patent, the '502 Patent, and the '648 Patent

The Final ID found that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on "Lumidigm,"[15] but claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent would not have been invalid as obvious over those combinations. *E.g.*, Final ID at 88, 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission affirms the Final ID's conclusions as to obviousness with the modifications and supplements discussed herein.

1. The Applicable Law

A party cannot be held liable for infringement if the asserted patent claim is invalid. *See Pandrol USA, LP v. AirBoss Ry. Prods., Inc*., 320 F.3d 1354, 1365 (Fed. Cir. 2003). Patent claims are presumed valid (35 U.S.C. § 282), so a respondent challenging validity must overcome this statutory presumption by "clear and convincing" evidence of invalidity. *Checkpoint Sys., Inc. v. Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995). One such ground for invalidity is that the claimed invention would have been obvious under 35 U.S.C. § 103.

Under 35 U.S.C. § 103(a), a patent is valid unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made" to a person having ordinary skill in the art. 35 U.S.C. § 103(a). The ultimate question of obviousness is a question of law, but "it is well understood that there are factual issues underlying the ultimate obviousness decision."

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[15] U.S. Patent No. 7,620,212 (RX-0411), titled "Electro-Optical Sensor," which issued from an application filed on August 12, 2003.

Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

After claim construction:

> The second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness.

Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17). The existence of secondary considerations, or objective indicia of non-obviousness, does not control the obviousness determination, because a court (and the Commission) must consider "the totality of the evidence" before reaching a decision on obviousness. *Richardson-Vicks*, 122 F.3d at 1483.

The Supreme Court clarified the obviousness inquiry in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 389 (2007). There, the Supreme Court said:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida*[16] and *Anderson's-Black Rock*[17] are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.
>
> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple

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[16] *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976).

[17] *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969).

> substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.
>
> . . .
>
> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at 417–19.

The Federal Circuit has since held that when a patent challenger contends that a patent is invalid for obviousness based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

> The TSM[18] test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the

[18] "TSM" is an acronym for "teaching, suggestion, or motivation."

> time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008).

2. Introduction

a. Lumidigm

Lumidigm is titled "Electro-Optical Sensor." *See* RX-0411 (Lumidigm). Lumidigm's Abstract is reproduced below:

> Methods and systems are provided that extend the functionality of electro-optical sensors. A device has . . . multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

RX-0411 (Lumidigm) at Abstract.

Figure 2 of Lumidigm is reproduced below:

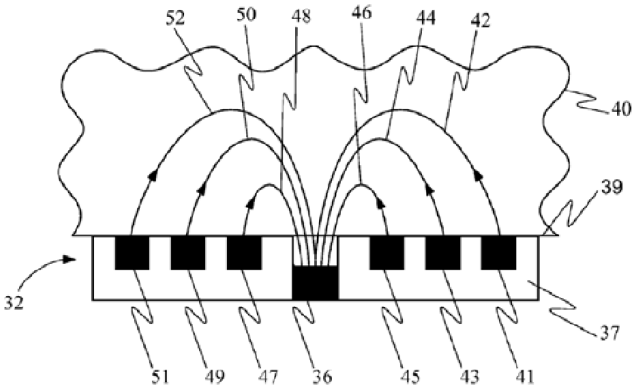

FIG. 2

RX-0411 (Lumidigm) at Fig. 2. Figure 2 depicts a "cross-sectional view of a biometric sensor element couple[d] to a tissue surface showing multiple mean optical paths." *Id.* at 4:45–47.

Sensor head 32 includes light sources 41, 43, 45, 47, 49, and 51 and detector 36. *Id.* at 7: 5–10. These light sources correspond to the claimed "LEDs," and detector 36 corresponds to a claimed "photodiode." Optical paths 42, 44, 46, 48, 50, and 52 show light passing through tissue 40 of a user. *Id.* Sensor head 32 is formed of optically opaque material 37, corresponding to the claimed "opaque material."

Figures 6 and 7A of Lumidigm are reproduced below:

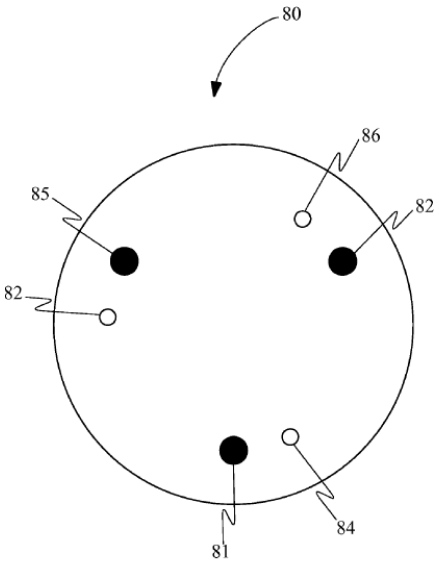

FIG. 6

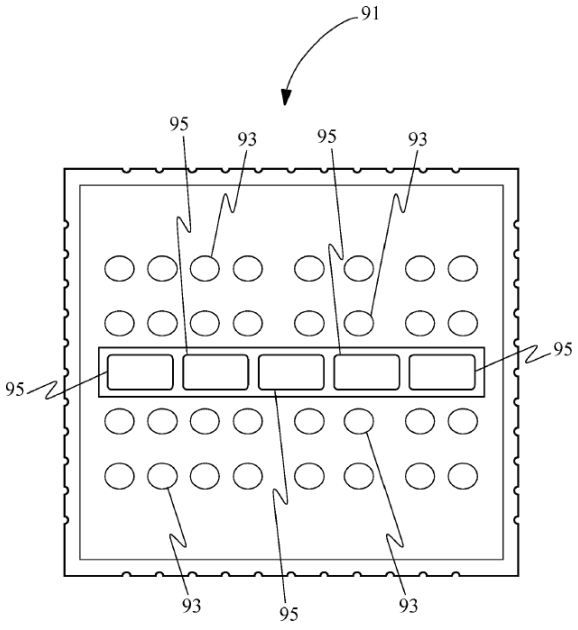

FIG. 7A

RX-0411 (Lumidigm) at Figs. 6 and 7A. Figures 6 and 7A illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, biometric sensor 80 includes light sources/LEDs 82, 84, and 86 positioned relative to detectors/photodiodes

81, 83,[19] and 85. *Id.* at 9:14–17. In Figure 7A, biometric sensor 91 includes four rows of light sources/LEDs 93 and one row of detectors/photodiodes 95. *Id.* at 9:27–30.

Figure 8B, reproduced below, depicts a wrist-watch embodiment:

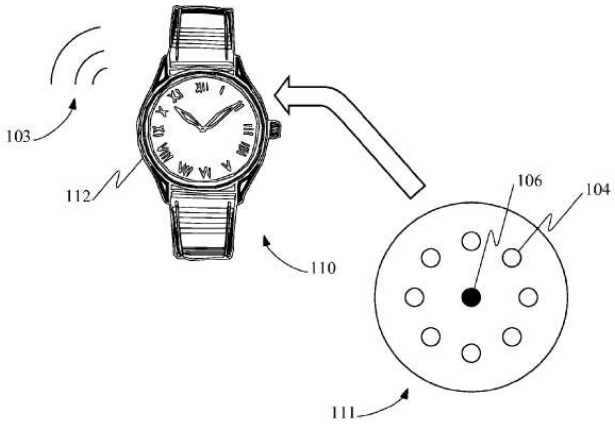

FIG. 8B

RX-0411 (Lumidigm) at Fig. 8B (depicting biometric system 110 including wristwatch 112, biometric reader 111, illumination system 104, and detection/diode system 106).

b. Summary of the Commission's Conclusions

As noted above, the Final ID found that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent would not have been invalid as obvious over those combinations. *E.g.*, Final ID at 88, 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244.

On review, the Commission affirms the Final ID's findings as to *prima facie* obviousness of claim 12 of the '501 patent in its entirety. *See* Final ID at 89–113. Secondary considerations are discussed separately below.

[19] The item number "82" for the dark circle at approximately 2 o'clock of Figure 6 is a typographical error. It is apparent that that item number was intended to be "83."

Regarding claim 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent, these claims recite, *inter alia*, a “user-worn device” comprising (1) “four photodiodes,” (2) a “protrusion,” (3) an “opening” or “through hole” “extending through” or “provided through” the protrusion and “aligned with” or “over” each of the four photodiodes, and (4) a separate “transmissive window” or “optically transparent material” “extending across” or “arranged over” each of the openings or though holes. *See* JX-0002 (’502 patent) at claim 28, elements [28C], [28E], [28F], and [28G]; JX-0003 (’648 patent) at claim 12, elements [8C], [8D], [8E], and [8F], and claims 24 and 30, elements [20B], [20C], and [20D]. Claim 22 of the ’502 patent is similar, but more narrowly requires that an “optically transparent material” be included “*within* each of the openings.” *See* JX-0002 (’502 patent) at claim 22, elements [19B], [19C], and [19D].

The Commission concludes that Lumidigm and combinations of references therewith teach or suggest (1) the four photodiodes, and (2) the protrusion, but the combinations of references do not teach or suggest (4) a separate transmissive window or optically transparent material within, extending across, or over each of the openings or though holes. The Commission, however, takes no position on the Final ID’s finding that the combinations of references do not teach or suggest (3) an opening or through hole extending through or provided through the protrusion and aligned with or over each of the four photodiodes. *See Beloit*, 742 F.2d at 1423. In doing so, the Commission slightly modifies the Final ID, as discussed below.

Regarding claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent, these claims also recite, *inter alia*, various limitations directed at the claimed user-worn devices being configured to measure the oxygen saturation of the user. JX-0002 (’502 patent) at claim 22, elements [19PRE] and [19E], and at claim 28, elements [28PRE], [28I], [28J], and

[28K]; JX-0003 ('648 patent) at claim 12, elements [12], and claims 24 and 30, element [20E].[20] The Final ID found that neither Lumidigm nor combinations therewith teach or suggest these claim limitations. *See* Final ID at 113–18, 124, 128, 132–33, 140, 142. The Final ID also found that element [24] of claim 24 of the '648 patent was not taught or suggested by Lumidigm or combinations of references therewith. *See id.* at 142–44. The Commission affirms these findings for the reasons given in the Final ID.

Regarding the Final ID's analysis of objective indicia of non-obviousness, the Commission alters the Final ID's findings as to commercial success, and it does so by affirming those findings with the modifications discussed below.

Because the Commission modifies or supplements the Final ID's findings as to the *prima facie* obviousness and/or secondary considerations of these claims, the Commission evaluates anew (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness. In doing so, the Commission concludes, as did the Final ID, that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent are not invalid as obvious over those combinations of references.

Below, the Commission provides its analysis regarding *prima facie* obviousness of the above-mentioned structural limitations, and then discusses the objective evidence of non-

[20] As the Final ID noted, the parties stipulated that the preambles of the asserted patents are limiting. *See* Final ID at 180 n.66.

obviousness. Last, the Commission provides its analysis as to whether, in view of its underlying findings, Apple has shown by clear and convincing evidence that the asserted claims of the Poeze patents are invalid. In sum, the Commission concludes that Apple has not met its burden, except with respect to claim 12 of the '501 patent. The Commission affirms the Final ID as to *prima facie* obviousness and secondary considerations over Lumidigm and combinations of references therewith to the extent it is not modified or reversed herein.

3. *Prima Facie* Obviousness Over Lumidigm and Combinations Therewith

a. The "Openings" or "Through Holes" Limitations

As noted above, the claims recite an "opening" or "through hole" "extending through" or "provided through" the protrusion and "aligned with" or "over" each of the photodiodes. More specifically, the claims recite (with added emphasis) as follows:

- Element [1D] of claim 12 of the '501 patent: "*a plurality of openings extending through the protrusion and positioned over the three photodiodes*."
- Element [19C] of claim 22 of the '502 patent: "a protrusion comprising a convex surface[21] including *separate openings extending through the protrusion* and lined with opaque material, *each opening positioned over a different one of the four photodiodes*."
- Element [28F] of claim 28 of the '502 patent: "*a plurality of openings* in the convex surface, *extending through the protrusion*, and *aligned with the four*

[21] The Commission affirms the Final ID's finding that Lumidigm combined with prior art knowledge teaches or suggests a "protrusion" having a "convex surface." *E.g.*, Final ID at 101–03. The Final ID found that known ergonomic and contact benefits would provide persons of ordinary skill in the art a reason to modify Lumidigm to include a convex surface, as argued by Apple. *See id.*

photodiodes, each opening defined by an opaque surface configured to reduce light piping."

- Element [8E] of claim 12 of the '648 patent: "a *plurality of openings provided through the protrusion* and the convex surface, *the openings aligned with the photodiodes*."
- Element [20D] of claims 24 and 30 of the '648 patent: "a *plurality of through holes*, each through hole including a window and *arranged over a different one of the at least four photodiodes*."

i. The "Openings" in the "Three Photodiode" Claim (Claim 12 of the '501 Patent)

The Final ID first analyzed the "openings" limitations in its discussion of claim 12 of the '501 patent, which claims a "user-worn device" that, unlike the other asserted claims of the Poeze patents, has "at least three photodiodes," as opposed to "four photodiodes." The "openings" limitation of that claim is included in element [1D], which recites "a plurality of openings extending through the protrusion and positioned over the three photodiodes." *See* JX-0001 ('501 patent) at claim 12, element [1D]. The Final ID found that Lumidigm teaches or suggests this limitation, *see* Final ID at 104–06, contrary to its conclusions as to the four photodiode claims, *see id.* at 120–21, 130, 139, 142.

Before the ALJ, Apple argued that element [1D] of the '501 patent was taught by Lumidigm because Lumidigm expressly states that photodiode/detector 36 in Figure 2 (annotated version provided below showing detector 36 in purple) "may comprise . . . a plurality of discrete elements" and Figure 6 (annotated version also provided below) illustrates an embodiment having three such detectors (also shown in purple). *See* RPHBr. at 76.

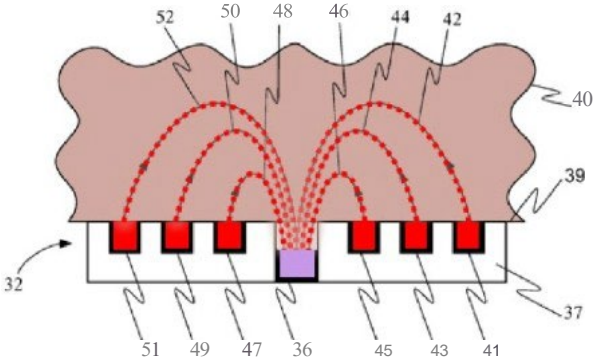

FIG. 2

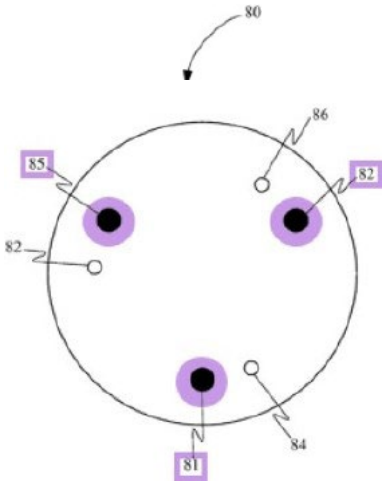

FIG.6

RX-0411 (Lumidigm) at Fig. 2 and Fig. 6 (identifying light sources/LEDs 82, 84, and 86 and detectors/photodiodes 81, 82 [sic],[22] and 85). For their part, Complainants argued that element [ID] was not met because Figure 2, which undisputedly shows a side view "opening" over a single photodiode, is allegedly in no way linked to Figure 6, which shows a top-down view of three photodiodes. *See* CPHBr. (Reply) at 48.

The Final ID accepted Apple's arguments, reasoning that "Figure 2 co1Tesponds to the source-detector anangement of Figure 3, and that … anangement of three sources and three detectors in Figure 6 is a disclosed alternative to Figure 3." *See* Final ID at 105-06. Figure 3 is reproduced below.

[22] As noted above, item number 82 should be item number 83.

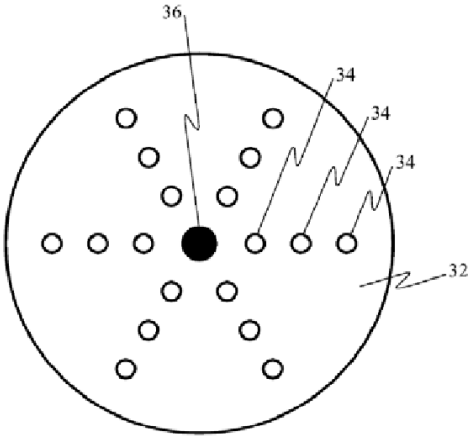

FIG. 3

RX-0411 (Lumidigm) at Fig. 3 (depicting photodiodes/detectors 36 and LEDs/light sources 34). The Final ID therefore determined that element [1D] was met. *See id.*

No party petitioned for the Commission to review this finding, so the Commission has determined to affirm this finding.

ii. The Openings in the "Four Photodiode" Claims

The Final ID found that the openings or through holes limitations in elements [19C] and [28F] of the '502 patent and elements [8E] and [20D] of the '648 patent were not taught or suggested by the prior art.

Before the ALJ, Apple argued that Lumidigm explains that, for any of the "reflectance" type sensor heads shown in its figures, reflected light on the top surface of the tissue can be "detrimental" to optical measurements, and thus the detectors should be "recessed from the sensor surface" in "optically opaque material" to "minimize[ ] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue" and to provide "optical blocking." RPHBr. at 72–74, 82–83 (quoting and citing RX-0411 (Lumidigm) at 7:64–8:1). Apple further argued that a person of ordinary skill in the art would have understood that, for the

embodiments with multiple photodiodes, the protrusion would include separate openings positioned over each of the photodiodes. RPHBr. at 75–77, 83.

The Final ID disagreed with Apple, finding that the evidence does not show that the "array"-type detectors in Lumidigm relied upon by Apple for element [19B] of the '502 patent for identification of the "four photodiodes" would be formed with "separate openings" through the protrusion for individual photodiodes in the array, as required by element [19C] of the '502 patent. Final ID at 120–21 (citing RPHBr. at 82; CPHBr. at 143; CPHBr. (Reply) at 55). The Final ID also rejected Apple's argument that these limitations are obvious based on the combination of Lumidigm with Cramer. *E.g.*, Final ID at 121.

Apple petitioned for the Commission to review these findings. RPet. at 21–26.

The Commission has determined to take no position as to the openings or through holes limitations of the asserted claims of the '502 patent and '648 patent. *See Beloit*, 742 F.2d at 1423. Specifically, the Commission has determined to take no position on the Final ID's findings as to the following "openings" and "through hole" limitations: (1) element [19C] of claim 22 of the '502 patent: "a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, *each opening positioned over a different one of the four photodiodes*"; (2) element [28F] of claim 28 of the '502 patent: "a plurality of openings in the convex surface, extending through the protrusion, and *aligned with the four photodiodes*, each opening defined by an opaque surface configured to reduce light piping"; (3) element [8E] of claim 12 of the '648 patent: "a plurality of openings provided through the protrusion and the convex surface, *the openings aligned with the photodiodes*"; and (4) element [20D] of claims 24 and 30 of the '648 patent: "a plurality of

through holes, each through hole including a window and *arranged over a different one of the at least four photodiodes*."

As explained below, the Commission affirms the Final ID's findings that Lumidigm and combinations therewith fail to teach or suggest several other limitations in claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. The Commission therefore takes no position on whether Lumidigm, or Lumidigm in combination with other prior art references, discloses the openings or through holes limitations of the '502 and '648 patents.

b. The "Transmissive Window" or "Optically Transparent Material" Limitations

The asserted claims of the '502 and '648 patents also recite a separate "transmissive window" or "optically transparent material" "within," "extending across," or "arranged over" each of the "openings" or "though holes." More specifically, the claims recite as follows:

- Element [19D] of claim 22 of the '502 patent: "optically transparent material within each of the openings."
- Element [28G] of claim 28 of the '502 patent: "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings."
- Element [8F] of claim 12 of the '648 patent: "a separate optically transparent window extending across each of the openings."
- Element [20D] of claims 24 and 30 of the '648 patent: "each through hole including a window and arranged over a different one of the at least four photodiodes."

The Final ID found that the "extending across" and "arranged over" limitations (element [28G] of claim 28 of the '502 patent, element [8F] of claim 12 of the '648 patent, and element

[20D] of claims 24 and 30 of the '648 patent) were taught by Lumidigm or combinations therewith, but that the "within" limitation (element [19D] of claim 22 of the '502 patent) was not. *See* Final ID at 130 (element [28G] of claim 28 of the '502 patent), 139 (element [8F] of the '648 patent), 142 (element [20D] of claims 24 and 30 of the '648 patent), 121–24 (element [19D] of claim 22 of the '502 patent).

As discussed below, on review, the Commission finds that none of these limitations are taught by Lumidigm or combinations therewith.

i. Element [19D] of Claim 22 of the '502 Patent

a) The Final ID

With respect to element [19D] of the '502 patent (an "optically transparent material within each of the openings"), Apple identified as the "optically transparent material" Lumidigm's disclosure of an "optical relay" positioned "between the sensor surface 39 and the skin 40" that "transfers the light . . . from the skin back to the detector(s)." RPHBr. at 84–85; RX-0411 (Lumidigm) at 8:19–23; Final ID at 121. Lumidigm provides examples of "optical relays," including "fiber-optic face plates and tapers, individual optical fibers and fiber bundles, light pipes and capillaries, and other mechanisms known to one of skill in the art." RX-0411 (Lumidigm) at 8:23–26; *see also* Final ID at 121–22. Apple relied on Dr. Warren's testimony that one of ordinary skill in the art would have understood an "optical relay" to be an optically transparent material. RPHBr. at 84–85; Final ID at 122; Tr. (Warren[23]) at 1221:16–1222:25. Apple further argued that these limitations would be obvious because the use of optically transparent materials within openings

[23] Steven Warren was admitted as an Apple expert witness in biomedical engineering, medical monitoring systems, biomedical instrumentation, biomedical optics, light issue interaction, diagnostic systems, wearable sensors, and biomedical signal processing. *E.g.*, Final ID at 6–7.

over photodiodes and the use of transmissive or transparent windows arranged over or extending across openings over photodiodes was well-known at the time of the Poeze patents. RPHBr. at 111–13; Tr. (Warren) at 1193:23–1194:14, 1221:16–1222:9; RDX-8C at .11 (citing, *inter alia*, RX-0670 (Cramer[24]); RX-0665 (Nippon[25]); RX-0666 (Seiko 131[26]); RX-1221 (CLT 2160[27]); *see also* Final ID at 122–23. According to Apple, a person of ordinary skill in the art would have been motivated to combine Lumidigm's wristwatch with teachings from Seiko 131 and Cramer because "(1) Lumidigm expressly states that its sensor can include an optical relay; and (2) a [person of ordinary skill in the art] would have independently looked to literature like Seiko 131 and Cramer for this element as the benefits were well-known." RPHBr. at113. Those alleged benefits are protecting the photodiodes from dirt and helping to transfer light. *E.g.*, RResp. at 17–18 (citing Tr. (Warren) at 1193:24–1194:14, 1221:16–1222:9).

For their part, Complainants argued that Lumidigm's disclosure of an "optical relay" does not meet the "optically transparent material" limitation and, in any event, is not disclosed in connection with Lumidigm's wristwatch embodiment. CPHBr. at 138–39 (citing Tr.

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[24] U.S. Patent No. 4,224,948, titled "Wrist Borne Pulse Meter/Chronometer," issued to Frank B. Cramer, *et al.*, on September 30, 1980, from an application filed on November 24, 1978 (RX-0670).

[25] U.S. Patent No. 4,880,304, titled "Optical Sensor for Pulse Oximeter," issued to Jonathan P. Jaeb, *et al*., on November 14, 1989, from an application filed on April 1, 1987 (RX-0665). The face of the patent indicates that Nippon is assigned to Nippon Colin Co., Ltd.

[26] U.S. Patent No. 5,766,131, titled "Pulse-Wave Measuring Apparatus," issued to Yutaka Kondo, *et al.*, on June 16, 1998, from an application filed on July 30, 1996 (RX-0666). The face of the patent indicates that Seiko 131 is assigned to Seiko Epson Corporation and Seiko Instruments, Inc.

[27] "CLT 2160" is a datasheet introduced by Apple. RX-1221. The Final ID found the datasheet to be reliable evidence. Final ID at 109 n.38.

(Madisetti[28]) at 1330:2–5); *see also* Final ID at 123. Complainants further argued that Seiko 131 fails to disclose multiple openings or optically transparent material within multiple openings. CPHBr. at 148–49; *see also* Final ID at 123. Complainants further argued that, with respect to Cramer, the alleged windows are between the annular rings and are not "within" the openings. CPHBr. at 146–47; *see also* Final ID at 123.

The Final ID found that Lumidigm clearly discloses "optically transparent material" over openings associated with photodiodes, but that the evidence does not clearly and convincingly show a reason to incorporate such material "within" each opening. Final ID at 123. According to the Final ID, Lumidigm describes an optical relay that is comprised of optically transparent material. *Id.* at 123 (citing RX-0411 (Lumidigm) at 8:19–26; Tr. (Warren) at 1221:16–1222:25). However, the Final ID found that the optical relay is not "within" the opening depicted in Figure 2, rather, it is located "between the sensor surface 39 and the skin 40." *Id.* (quoting RX-0411 (Lumidigm) at 8:19–26) (citing RX-0411 (Lumidigm) at Fig. 2).

The Final ID likewise found that Seiko 131 similarly discloses a "light transmittance plate" that is positioned above its sensor, but that plate is not "within" any opening. *Id.* at 123 n.47 (citing RX-0666 (Seiko 131), at 10:30–32). And the Final ID also found that Cramer discloses annular windows, but those windows do not appear to be associated within "each" opening. *Id.* (citing Tr. (Warren) at 1234:22–1235:12; RDX-8C at .73; RX-0670 (Cramer) at Fig. 6). The Final ID added that "Apple appears to have identified transparent windows within an opening in Cramer's preferred photodiode, the CLT 2160, but did not provide a clear and convincing reason to modify Lumidigm to include such material within the openings or to

[28] Vijay Madisetti is Complainants' expert witness and was admitted as an expert in the field of physiological monitoring technologies. Final ID at 6.

incorporate the CLT 2160 photodiode in Lumidigm." *Id.* at 123–24 (citing RX-0670 (Cramer) at 5:33–35, Fig. 6; RX-1221 (CLT 2160); RPHBr. at 112–13).

Apple petitioned for review of the Final ID's findings regarding Lumidigm alone and Lumidigm combined with Cramer. *See* RPet. at 96–97.

b) Apple's Petition

Regarding Lumidigm alone, Apple's petition argued that Lumidigm teaches an optical relay to "transfer[ ] the light from the light sources to the skin and from the skin back to the detector(s) while minimizing light loss and spreading." RPet. at 96 (quoting RX-0411 (Lumidigm) at 8:19–26) (citing Tr. (Warren) at 1221:16–1222:25, 1235:14–1236:2). Apple further asserted that a person of ordinary skill in the art would have understood that an optical relay could be added to Lumidigm's sensor. *Id.* (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; Tr. (Warren) at 1221:16–1222:25). Apple further argued that a person of ordinary skill in the art would have further understood that the optical relay could be placed over or within the openings to "transfer light" from the tissue to the photodiodes and "protect the detector from dust and debris and dirt." *Id.* (citing Tr. (Warren) at 1193:24–1194:7, 1221:16–1222:16).

Regarding Lumidigm in combination with Cramer, Apple argued that the "use of optically transparent materials extending across or within opening[s] associated with photodiodes was well known in the art prior to 2008 and taught by Lumidigm." RPet. at 97 (citing Tr. (Warren) at 1221:16–1222:9, 1193:24–1194:14; RX-0411 (Lumidigm) at 8:19–26, Fig. 2). Apple added that a person of ordinary skill in the art:

> would have naturally looked to other references in the field to improve on Lumidigm's teachings and would recognize the CLT 2160 taught by Cramer as a "can" detector and would understand that each can would include a lens at the top end of the can, that the detector would be positioned inside the can at the focal point of the lens, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens.

Id. (citing RX-0670 (Cramer) at Fig 6; Tr. (Warren) at 1231:23–1232:9, 1234:3–8, 1234:22–1235:12). Thus, according to Apple, a person of ordinary skill in the art would have been motivated to combine Lumidigm with Cramer because "Lumidigm expressly teaches the benefits of transparent material within openings over photodiodes and, more generally, because the benefits were well known." *Id.* (citing Tr. (Warren) at 1235:14–1236:2).

c) Complainants' Response

In response, Complainants argued that the evidence refutes Apple's argument that Lumidigm alone teaches or suggests that the optical relay would be *within* the opening. CResp. at 95 (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; Tr. (Madisetti) at 1330:2–5, 1343:1–4; Tr. (Warren) at 1221:16–1221:25) (emphasis added); Final ID at 123–24. Complainants presented a similar argument regarding the combination of Lumidigm with Cramer. *See id.* (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; RX-0670 (Cramer) at Fig. 6; Tr. (Madisetti) at 1330:2–5, 1334:15–1335:25, 1343:1–4; Tr. (Warren) at 1221:16–1221:25, 1235:24–1236:2); Final ID at 123–24 (including n.47). Complainants further pointed out that the USPTO, in denying institution of Apple's IPR petitions, found that "none of the prior art on which [Apple] relies[, including Lumidigm,] discloses a convex protrusion with multiple openings or windows for multiple detectors." *Id.* at 95–96 (citing CResp. Appx. A, at 17; Appx. B, at 16; Appx. C, at 16) (emphasis omitted).

Relatedly (but more specifically directed to element [28G] of claim 28 of the '502 patent),[29] Complainants argue that Apple's witness, Dr. Warren, testified only about what a

[29] Recall that that claim language recites: "a plurality of transmissive windows, each of the transmissive windows *extending across* a different one of the openings." This language differs from that of element [19D] of claim 22 of the '502 patent only in that it does not require the window or optically transparent material to be "*within*" the through holes or openings.

person of ordinary skill in the art *could do*, and not what such a person would have been motivated to do or have a reason to do. *E.g.*, CPet. (Summary) at 3 (citing Final ID at 131); *see also* CPet. at 23–24. Complainants argued that Apple provided no evidence that a person of ordinary skill in the art "*would have* modified Lumidigm's face plate into multiple windows with a reasonable expectation of success ([RPHBr.] at 84–85), and the [Final] ID made no findings regarding reasonable expectation of success for such a modification." CPet. (Summary) at 3 (citing Final ID at 131) (emphasis added); *see also* CPet. at 23–24.

d) Analysis

The Commission has determined to affirm and adopt the Final ID's findings and conclusion that neither Lumidigm nor a combination of Lumidigm and other prior art teaches or suggests an "optically transparent material *within* each of the openings." Final ID at 121–24. The Commission has considered Apple's arguments that the Final ID erred as to this limitation and finds them unpersuasive.

The Commission has further determined to supplement the Final ID. Beyond the prior art not teaching or suggesting the optically transparent material within each of the openings, Apple failed to show that the prior art provides a reason to use a separate optically transparent material or window for each of the separate openings or through holes. *See* CPet. at 23–24. First, none of the prior art cited by Apple teaches or suggests separate optically transparent materials (or windows), and Apple has not shown by clear and convincing evidence that a person of ordinary skill at the time of the claimed inventions would have arrived at these limitations, as claimed. Apple acknowledges that Lumidigm does not teach the separate optically transparent materials (or windows). *E.g.*, RResp. at 18–19 (relying on knowledge in the art to modify Lumidigm to arrive at separate windows). Moreover, neither Cramer nor Seiko 131 disclose the separate optically transparent materials (or windows). As the Final ID properly found, Apple has failed to

clearly and convincingly show that Cramer teaches or suggests a protrusion with separate openings or through holes over separate photodiodes. *See* Final ID at 103 n.36; CPHBr. at 144–46; Tr. (Warren) at 1231:18–22; Tr. (Madisetti) at 1334:23–1335:2. Thus, Cramer cannot teach separate optically transparent materials (or windows) within (or over or extending across) the claimed separate openings or through holes. Additionally, Complainants correctly point out that Seiko 131 discloses only a singular phototransistor and light transmittance plate and thus does not teach the separate optically transparent materials (or windows) within (or over or extending across) the claimed separate openings or through holes. *See* CPHBr. at 148–50. CLT 2160 similarly discloses only a single window and photodiode. *See* RX-1221 (CLT 2160).

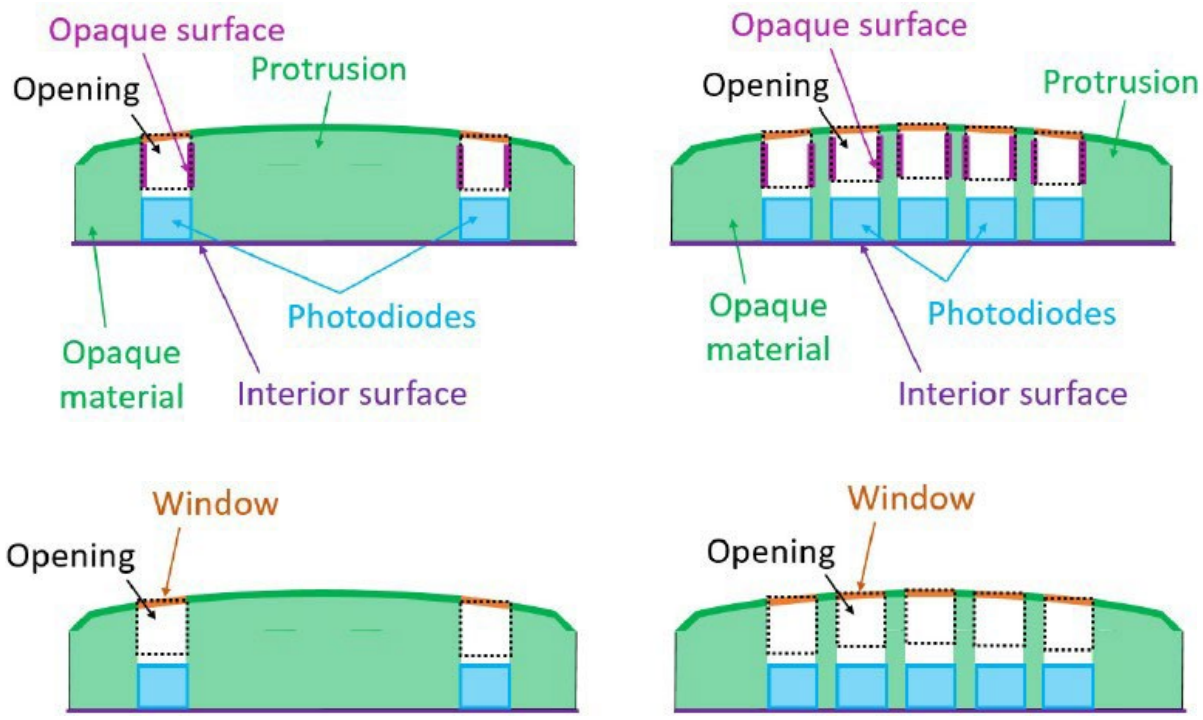
Second, Apple has not shown by clear and convincing evidence that, at the time of the claimed inventions, a person of ordinary skill in the art would have had a reason to use a separate optically transparent material (or window) within (or over or extending across) each of the separate openings (or through holes). As Complainants point out, Dr. Warren testified only about what a person of ordinary skill in the art *could* do, not what such a person *would* do. *See* CPet. (Summary) at 3; CPet. at 23–24; *see also* RPet. at 96–97 (discussing and citing Dr. Warren's testimony); Tr. (Warren) at 1193:24–1194:14 (stating only that windows were well known); *id.* at 1221:16–1222:25 (stating only a person of ordinary skill in the art "*could use*" an individual faceplate for each of the individual openings (emphasis added)); *id.* at 1235:24–1236:2 (stating that a person of ordinary skill in the art "would have known that windows *could be used*" (emphasis added)). Apple's asserted motivation for including the optical relay (allowing for the transfer of light and to protect the detector from dust and dirt), could be obtained with a single optically transparent material (or window) over the surface, as opposed to separate optically transparent materials (or windows). And, Apple's "convoluted combination of

modifications" is driven by improved contact and comfort from the claimed "convex surface," yet Apple has not shown why that improved contact and comfort would remain with the further modification to have multiple distinct openings and windows. *See Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at Appx. C) (discussed below); Final ID at 101–03 (finding that a person of ordinary skill in the art would be motivated to implement a convex surface to obtain better contact and comfort). Moreover, as noted above, neither Cramer nor Seiko 131 teach the separate optically transparent material (or windows), and Apple points to no specific teachings of those references, or any other reference, that suggests using separate optically transparent materials (or windows). Apple has thus failed to present clear and convincing evidence that a person of ordinary skill in the art *would have* implemented Lumidigm's "optical relay" as separate optically transparent materials (or windows) within (or over or extending across) each of the separate openings (or through holes), as opposed to a single optical relay covering the entire convex surface. *See, e.g.*, RResp. at 17–19; RPet. at 96–97; Final ID at 121–24.

Although not binding on the Commission,[30] the Commission notes that its decision herein is consistent with the USPTO's denial of Apple's petitions for an IPR to review claims 1–30 of the '502 patent over combinations of references where Lumidigm serves as the primary reference. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at

[30] *See, e.g.*, *Certain Hybrid Electric Vehicles & Components Thereof*, Inv. No. 337-1042, Notice of Investigation at 1 (Mar. 7, 2017) (Commission instituting investigation over proposed Respondents' objection that asserted claims had been found unpatentable in IPR proceedings and were on appeal to Federal Circuit).

Appx. C). There, Apple argued that based on the combined teachings of Lumidigm and "Kotanagi"[31] the following figures emerge:



Id. at 15.

In this investigation, Apple's Lumidigm-based theories of obviousness rely on the same modified version of Lumidigm. In denying institution, the USPTO agreed with Complainants that "none of the prior art on which [Apple] relies discloses a convex protrusion with multiple openings or windows for multiple detectors," and that Apple "simply does not explain adequately why such configuration results from the actual teachings of the prior art." *Id.* at 16; *see also id.* at 16–19. The USPTO reasoned that, "[w]ithout the guidance provided by the claims of the '502 patent, it is difficult to conclude that [Apple's] postulation as to a particular structure

[31] PCT Application No. WO 2005/092182.

that results from combining the teachings of Lumidigm [and the other prior art] is based on an objective assessment of what those teachings would have conveyed to a skilled artisan." *Id.* at 16. In other words, Apple's arguments there were "grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art." *Id.* at 19. The same is true here.

While Apple alleges that both the evidentiary record and the obviousness theory before the USPTO and the Commission are different, *see* RResp. at 17 n.4, there are no notable differences. The above-shown modification of Lumidigm presented to the USPTO is based almost entirely on Lumidigm, *see Apple*, IPR2022-01274 at 16–19 (available at CResp. at Appx. C), as is Apple's Lumidigm-based obviousness theory in this investigation. And while Apple relied on Kotanagi for the "convex surface" modification of Lumidigm before the USPTO (as opposed to other knowledge in the prior art, as it does before the Commission), Apple relied on the same reason for that modification of Lumidigm both before the USPTO and here—"better contact" and "comfort." *Compare id.* at 16–17, *with* Final ID at 99, 101–02 (incorporating ergonomic features and optical and mechanical coupling). Accordingly, the Commission's rejection of Apple's Lumidigm-based theory for the obviousness of claim 22 of the '502 patent is consistent with the USPTO's denial of Apple's petition to institute an IPR over combinations of references involving Lumidigm.[32]

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[32] Complainants assert that the USPTO's denial of the institution of Apple's petition for an IPR over Lumidigm-based combinations of references as to the claims of the '501 patent suggests that the Commission should also reverse the Final ID as to its obviousness finding as to claim 12 of the '501 patent. CResp. at 3 n.2. However, in Apple's petition related to the '501 patent and Lumidigm, Apple's theory was different than the Lumidigm-based theory that it presented in this investigation as to the '501 patent. Significantly, in that petition, Apple presented a Lumidigm-based theory that is similar to the one it presents in this investigation as to the asserted claims of the '502 and '648 patents (*see Apple Inc. v. Masimo Corp.*, IPR 2022-01272 (USPTO Jan. 24, 2023) (available at CResp. at Appx. B)), which as discussed in this section, lacks a reason for a person of ordinary skill in the art to arrive at the claimed subject

ii. Element [28G] of the '502 Patent—"Each of the Transmissive Windows Extending Across a Different One of the Openings"

a) The Final ID

Regarding element [28G] of claim 28 of the '502 patent, which uses the phrase "extending across," the Final ID found that Lumidigm discloses an "optical relay" that is transmissive and is positioned above an opening for a detector. Final ID at 131 (citing RX-0411 (Lumidigm) at 8:19–26; Tr. (Warren) at 1221:16–1222:25). The Final ID recognized that Lumidigm discloses a single window, but found, based on Dr. Warren's testimony, that "a person of skill would know that you could do an individual faceplate for each of the individual openings as a means to provide light but still optimize the process." *Id.* (citing, *inter alia*, Tr. (Warren) at 1221:1–1222:25, 1193:23–1194:14; RDX-8C at .11; RX-0670 (Cramer); RX-0666 (Seiko 131)).

Complainants petitioned for review the Final ID's findings regarding Lumidigm. *See* CPet. at 23–24.

b) Complainants' Petition

Complainants' petition is largely the same as its argument discussed in the previous section. Complainants argued that the Final ID "legally erred by finding that Lumidigm satisfied the requirements of Element [28G] based on [Dr.] Warren's testimony about what a [person of ordinary skill in the art] 'could do.'" CPet. (Summary) at 3 (quoting Final ID at 131); *see also* CPet. at 23–24. Complainants further argued that the Final ID also legally erred because Apple

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matter. In other words, while claim 12 of the '501 patent does not recite the separate windows, Apple's IPR petition depended on proving that a person of ordinary skill in the art would arrive at a device that contained that limitation.

provided no evidence that a person of ordinary skill in the art "would have modified Lumidigm's face plate into multiple windows with a reasonable expectation of success ([RPHBr.] at 84–85), and the [Final] ID made no findings regarding reasonable expectation of success for such a modification." CPet. (Summary) at 3 (citing Final ID at 131); *see also* CPet. at 23–24. Complainants further argue that "[t]he Patent Office's recent rejection of Apple's IPR petitions challenging the Poeze Patents confirms that Apple's obviousness theories are without merit and based in hindsight." CResp. at 8.

c) Apple's Response

Apple's response is also largely the same argument as the one discussed in the previous section. According to Apple, Dr. Warren explained that this limitation was known in the prior art "both to help transfer light and to protect the photodiodes from dirt or debris." RResp. at 17–18 (citing Tr. (Warren) at 1193:24–1194:14, 1221:16–1222:9; RX-0411 (Lumidigm) at 8:19–23). Apple also relied on Dr. Warren's testimony that the listed examples were well known "and could be placed within or arranged over the openings to transfer light and to protect the photodiodes." *Id.* at 18–19 (quoting Tr. (Warren) at 1221:16–1222:25). Apple further argued that a person of ordinary skill in the art would have "understood that the fiber optics face plates referenced in Lumidigm could be implemented as a single faceplate or as individual faceplates over each opening and would have been motivated to implement either alternative." *Id.* at 19 (citing Tr. (Warren) at 1221:16–1222:25, 1193:24–1194:14).

d) Analysis

For the reasons discussed above as to element [19D] of the '502 patent, the Commission finds that Apple has not shown, by clear and convincing evidence, that, at the time of the claimed invention, the prior art teaches separate transmissive windows for each of the openings or that a person of ordinary skill in the art would have had any reason or motivation to arrive at this

limitation, as claimed. Additionally, for the same reasons noted above for element [19D] of the '502 patent, the Commission's determination is consistent with the USPTO's denial of Apple's petition requesting the institution of an IPR proceeding regarding the claims of the '502 patent. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at Appx. C).

iii. Element [8F] of Claim 12 of the '648 Patent—"A Separate Optically Transparent Window Extending Across Each of the Openings"; and Element [20D] of Claims 24 and 30 of the '648 Patent—"Each Through Hole Including a Window and Arranged Over a Different One of the at Least Four Photodiodes"

Regarding element [8F] of claim 12 of the '648 patent, which also uses the phrase "extending across," the Final ID held:

> For the same reasons discussed above in the context of the "plurality of openings" limitations of '502 patent claim 19 (Element [19C]), the evidence fails to show, clearly and convincingly, a "plurality of openings" with a "separate optically transparent window extending across each of the openings" in combination with the "four photodiodes" embodiments of Lumidigm relied upon by Apple.

Final ID at 139 (citing RPHBr. at 82, 91, 98). The Final ID made a similar conclusion regarding element [20D] of claims 24 and 30 of the '648 patent. *See* Final ID at 142. Thus, while the Final ID found that, *e.g.*, "a separate optically transparent window extending across each of the openings" limitation was taught (consistent with its finding as to element [28G] of the '502 patent, *see id.* at 131), the Final ID found that that limitation was not taught in a "four photodiode" embodiment having, *e.g.*, "openings aligned with the [four] photodiodes," *see, e.g.*, *id.* at 120–21.

As noted above, the Commission has determined to take no position as to the Final ID's underlying finding that the openings in these claims (elements [19C] and [28F] of the '502 patent

and elements [8E] and [20D] of the ’648 patent) were not taught or suggested by the prior art. However, the Commission has determined to affirm the Final ID for the alternative basis that because, for the reasons discussed above as to element [19D] of claim 22 of the ’502 patent and element [28G] of claim 28 of the ’502 patent, Apple did not present clear and convincing evidence that, at the time of the claimed invention, the prior art taught the claimed separate optically transparent windows extending across each of the openings, or that a person of ordinary skill in the art would have had any reason or motivation to arrive at this limitation. Additionally, for the same reasons noted above for element [19D] of the ’502 patent and element [28G] of claim 28 of the ’502 patent, the Commission’s determination is consistent with the USPTO’s denial of Apple’s petition requesting the institution of an IPR proceeding regarding the claims of the ’648 patent. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01276 (USPTO Jan. 30, 2023) (available at CResp. at Appx. A).

iv. Conclusions Regarding *Prima Facie* Obviousness and the Asserted Claims of the ’501, ’502, and ’648 Patents

In sum, regarding *prima facie* obviousness and the asserted claims of the ’502 and ’648 patents, the Commission concludes that, although Lumidigm and combinations of references therewith teach or suggest (1) the four photodiodes and (2) the protrusion, the combinations of references do not teach or suggest (4) a separate “transmissive window” or “optically transparent material” “within,” “extending across,” or “arranged over” each of the openings or though holes. The Commission takes no position on whether Lumidigm and combinations of references therewith teach or suggest an opening or through hole extending through or provided through the protrusion and aligned with or over each of the four photodiodes. Thus, Apple has not shown by clear and convincing evidence that these claims are *prima facie* obvious.

Regarding claim 12 of the '501 patent, the Commission affirms the Final ID's conclusion that Apple has shown by clear and convincing evidence that this claim is *prima facie* obvious.

4. Objective Evidence of Non-Obviousness

a. Introduction

As noted above, the Commission must consider "the totality of the evidence" before reaching a decision on obviousness, and that totality of evidence includes the existence of secondary considerations, or objective indicia of non-obviousness. *E.g.*, *Richardson-Vicks*, 122 F.3d at 1483.

Also, as noted above, before the ALJ, Complainants presented evidence of objective indicia of non-obviousness that allegedly showed the following: (1) skepticism and unexpected results related to the "convex protrusion" claim limitations; (2) skepticism and failures of others related to measuring pulse oximetry at the wrist; (3) Apple's alleged copying of Masimo's technology; and (4) the commercial success of the Apple Watch products once Apple implemented that technology. *See, e.g.*, Final ID at 145–56, 240–241.

Regarding Complainants' evidence, the Final ID agreed with Apple that Complainants failed to show that there was skepticism in the industry regarding convex surfaces. *See* Final ID at 147. And regarding Complainants evidence of skepticism and failures of others related to measuring pulse oximetry at the wrist, the Final ID found that this evidence does not significantly show non-obviousness because the asserted claims apply to any "user-worn device," including user-worn devices that are not worn on the wrist. *Id.* at 150–51. As for copying, the Final ID found that there was no significant credible evidence that Apple copied Masimo's patented technology. *Id.* at 153–54. Last, regarding commercial success, because the Final ID found that "there is little evidence of a significant nexus between Apple's commercial success and the allegedly non-obvious features of the asserted Poeze patent claims," the Final ID

found that this evidence "does not meaningfully affect the obviousness analysis." *Id.* at 156. Overall, the Final ID found that this evidence did not meaningfully alter the obviousness analysis. *See id.*

Complainants petitioned the Commission to review the Final ID's findings related to commercial success, *see* CPet. at 25–29; skepticism regarding convex surfaces, *id.* at 30–32; and skepticism regarding pulse oximetry at the wrist, *id.* at 33. Complainants did not petition for review of the Final ID's finding related to copying. *See generally id.* Accordingly, any such argument is waived. *Finnigan*, 180 F.3d at 1362–63.

The Commission has determined to affirm, without modifications, the Final ID as to (1) skepticism and unexpected results related to the "convex protrusion" claim limitations; (2) skepticism and failures of others related to measuring pulse oximetry at the wrist; and (3) Apple's alleged copying of Masimo's technology. Thus, the Commission adopts the Final ID's findings as to that evidence. For the reasons discussed below, the Commission has determined to affirm, with modifications, the Final ID's conclusion that Complainants' evidence of commercial success provides at most minimal weight due to the lack of a nexus to the claimed and novel features. *See* Final ID at 153–56.

b. Commercial Success

i. The Final ID

Before the ALJ, Complainants argued that the commercial success of the Apple Watch Series 6 and 7 is objective evidence of non-obviousness. CPHBr. at 173–75; CPHBr. (Reply) at 95–96; Final ID at 154–56. According to Daniel McGavock, Complainants' expert witness, sales of the Apple Watch Series 6 [redacted], and Apple advertised the blood oxygen feature as the key differentiator of the Series 6 over the previous series, Series 5. Tr. (McGavock) at 1416:10–21, 1422:8–1425:13; CX-0252; CX-1451; CX-

1532; CX-1289. Dr. Madisetti agreed with Mr. McGavock that there was a nexus between the blood oxygen feature of Apple Watch Series 6 and its commercial success. Tr. (Madisetti) at 1380:14–1381:4.

The Final ID found that the Apple Watch Series 6 was commercially successful and that "this may be due in some part to its blood oxygen monitoring features." Final ID at 155. The Final ID also found that the evidence does not persuasively indicate that the [redacted] "sales of the Apple Watch Series 6 are largely attributable to the blood oxygen feature, as market analysts have recognized the Apple Watch's 'blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps.'" *Id*. (quoting CX-1644 (Strategy Analytics)). The Final ID added that it is not "clear that the Apple Watch Series 6 was significantly more successful than other smartwatches." *Id*. (citing CX-1644 (Strategy Analytics)). According to the Final ID, the evidence "shows that much of the success of the Apple Watch Series 6 can be attributed to the growing market for smartwatches rather than the specific implementation of the pulse oximetry feature claimed in the patents-at issue." *Id*. (citing, *inter alia*, CX-1644 (Strategy Analytics)). Thus, the Final ID discounted Complainants' evidence of commercial success, finding that it does not "meaningfully affect the obviousness analysis." *Id*. at 155–56 (citing *Ormco Corp. v. Align Tech., Inc*., 463 F.3d 1299, 1313 (Fed. Cir. 2006)).

Because the Final ID found that "there is little evidence of a *significant nexus* between Apple's commercial success and the allegedly non-obvious features of the asserted Poeze patent claims, particularly for claim 12 of the '501 patent (which is not limited to blood oxygen measurements)," the Final ID found that this evidence "does not meaningfully affect the obviousness analysis above." Final ID at 156 (emphasis added).

As noted above, Complainants petitioned for review of this finding. *See* CPet. at 25–29.

ii. Complainants' Petition

In their petition for review of the Final ID, Complainants argued that the Final ID erroneously required that "there be a 'significant' nexus in order to be objective evidence of non-obviousness." CPet. at 25 (citing Final ID at 155, 156). According to Complainants, obviousness law does not require that "the patented invention be solely responsible for the commercial success[ ] in order for this factor to be given weight appropriate to the evidence." *Id*. at 26 (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.3d 1264, 1273 (Fed. Cir. 1991); *Apple Inc. v. Samsung Elecs. Co.*, *Ltd*., 839 F.3d 1034, 1055–56 (Fed. Cir. 2016) (en banc)). Next, Complainants argued that the Final ID made clearly erroneous factual findings regarding commercial success. CPet. at 26–29.

iii. Analysis

On review, the Commission has determined to affirm the Final ID with modifications. The Commission agrees with Complainants that the standard for "commercial success" does not require a showing of "significant nexus." *See* CPet. at 25. However, the Commission agrees with the Final ID that Complainants' evidence is consistent with increased sales of smartwatches in general and was likely based on the Apple Watches' "blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps." *See, e.g.*, Final ID at 155–56. Accordingly, the Commission concludes that Complainants' evidence of commercial success is entitled to minimal weight due to Complainants' failure to show a nexus between the alleged commercial success and the alleged claimed and novel features.

5. Overall Conclusion as to Obviousness

Because the Commission modifies and/or supplements the Final ID's findings as to the asserted claims of the Poeze patents regarding *prima facie* obviousness and/or secondary considerations, the Commission evaluates anew (1) the scope and content of the prior art, (2) the

level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness.

In doing so, the Commission concludes, as did the Final ID, that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but that claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent are not invalid as obvious over those combinations of references.

Regarding claim 12 of the '501 patent, Apple has shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. And, as discussed above, Complainants' objective evidence of non-obviousness has minimal weight. In view of these underlying findings, the Commission concludes that Apple has shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 28 of the '502 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. For example, Apple has failed to show that the prior art teaches or suggests elements [28PRE], [28G], [28I], [28J], and [28K]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 22 of the '502 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. Apple has failed to show that the prior art teaches or suggests elements [19PRE], [19D], and [19E]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings,

the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 12 of the ’648 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. Apple has failed to show that the prior art teaches or suggests elements [8F] and [12]. Also, Complainants’ evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claims 24 and 30 of the ’648 patent, Apple has not shown that these claims would have been *prima facie* obvious to a person of ordinary skill in the art. For example, Apple has failed to show that the prior art teaches or suggests elements [20D], [20E], and [24]. Also, Complainants’ evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that these claims would have been invalid by clear and convincing evidence.

C. Non-Obviousness of the Asserted Claims of the ’745 Patent

1. Introduction

The Final ID found that claims 9, 18, and 27 of the ’745 patent have not been shown to be invalid. Final ID at 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission affirms this finding with modifications.

Before the ALJ, Apple argued that claims 9 and 27 of the ’745 patent would have been obvious in view of the Apple Watch Series 0 and that claims 9, 18, and 27 of the ’745 patent

would have been obvious in view of U.S. Patent No. 8,670,819 to Iwamiya *et al*. (RX-0130[33]) in combination with U.S. Patent No. 9,392,946 to Sarantos *et al.* (RX-0366[34]) and U.S. Patent No. 8,998,815 to Venkatraman *et al*., (RX-0368[35]). *E.g.*, Final ID at 209.

Regarding claims 9 and 27 in view of the Apple Watch Series 0, the Final ID found that the prior art did not teach or suggest elements [1B], [1D], and [9] of claim 9 or elements [20B] and [20D] of claim 27. *See* Final ID at 212–14, 215–16, 218–20, 221, 222. Regarding claims 9, 18, and 27 and combinations based on Iwamiya, the Final ID found that the prior art did not teach or suggest element [9] of claim 9, element [18] of claim 18, and element [27] of claim 27. *See id.* at 228–31, 235–36, 239–40. Apple petitioned the Commission to review these findings. *See* RPet. at 62–70.

Complainants again presented objective evidence of non-obviousness. *See* CPHBr. at 233–34, CPHBr. (Reply) at 132–33. Complainants presented evidence allegedly showing Apple's skepticism and failures in implementing wrist-based pulse oximetry, the commercial success of the Apple Watch Series 6, and Apple's alleged copying of Masimo's technology. *See* CPHBr. at 233–34, CPHBr. (Reply) at 132–33. The Final ID concluded that, "[f]or the reasons discussed above in the context of the Poeze patents, this evidence does not weigh significantly against a finding of obviousness." Final ID at 241. The Final ID added that the "evidence of

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[33] U.S. Patent No. 8,670,819, titled "Optical Biological Information Detecting Apparatus and Optical Biological Information Detecting Method," issued to Hiroshi Iwamiya *et al*., on March 11, 2014, from an application filed on June 29, 2010.

[34] U.S. Patent No. 9,392,946, titled "Heart Rate Sensor with High-Aspect-Ratio Photodetector," issued to Chris H. Sarantos, *et al*., on July 19, 2016, from an application filed on May 28, 2015.

[35] U.S. Patent No. 8,998,815, titled "Wearable Heart Rate Monitor," issued to Subramaniam Venkatraman, *et al*., on April 7, 2015, from an application filed on June 3, 2014.

commercial success is not relevant because the Accused Products have not been shown to practice claims of the '745 patent." *Id.* at 241 n. 87. Complainants petitioned for review of the Final ID's findings as to Complainants' objective evidence of non-obviousness. *See* CPet. at 45.

Based on the totality of the evidence, the Final ID found that Apple did not show by clear and convincing evidence that the asserted claims of the '745 patent are obvious. Final ID at 240. Apple petitioned for review of this finding. *See* RPet. at 62–70.

As noted above, the Commission determined to review the Final ID's obviousness findings as to the '745 patent. 88 Fed. Reg. at 32244. On review, the Commission has determined to affirm the Final ID's findings regarding *prima facie* obviousness of the asserted claims of the '745 patent. The Commission has considered Apple's petition for review and found its arguments that the Final ID erred to be unpersuasive. As to Complainants' evidence of secondary considerations, the Commission has determined to affirm in part and reverse in part the Final ID for the reasons discussed below. After considering the totality of the evidence, the Commission has further determined to affirm the Final ID's finding that Apple has not shown that the asserted claims of the '745 patent are obvious.

2. Objective Evidence of Non-Obviousness

In their petition for review, Complainants point out that the Final ID rejected its arguments for the '745 patent "[f]or the reasons discussed above in the context of the Poeze patents." CPet. at 45 (quoting Final ID at 150). Complainants argue that the Final ID's reasoning for the Poeze patents as to skepticism and failures of others in implementing wrist-based pulse oximetry does not apply to claims 9 and 18 of the '745 patent. CPet. at 45 (quoting Final ID at 150). Complainants point out that the Final ID discounted Complainants' evidence regarding the claims of the Poeze patents because the Poeze claims are not limited to pulse oximetry at "the wrist." *Id.* (citing Final ID at 150). Complainants then argue that, on the other

hand, claims 9 and 18 of the '745 patent are limited to pulse oximetry at the wrist. *See id.*; *see also* JX-0009 ('745 patent) at claim 9, element [1B] ("a material configured to be positioned between the plurality of light-emitting diodes and tissue on *a wrist of a user* when the physiological monitoring device is in use" (emphasis added)); *id.* at claim 18, elements [15A] and [15B] ("a plurality of light-emitting diodes configured to emit light proximate *a wrist of a user*; a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on *the wrist of the user* when the physiological monitoring device is in use" (emphasis added)). Thus, according to Complainants, the Final ID "erred by failing to properly weigh the objective evidence of skepticism and failure of others in evaluating Claims 9 and 18." CPet. at 45.

The Commission agrees with Complainants. *See id.* Moreover, to the extent Apple disputes the Final ID's finding that Complainants have shown evidence of skepticism of Apple engineers regarding pulse oximetry at the wrist and the relevance thereof, *see* RResp. at 41–43, the Commission finds Apple's argument unpersuasive. The Final ID properly evaluated the evidence and arrived at its conclusion. In any event, this evidence does not meaningfully alter the obviousness analysis, as stated in the next sub-section.

The Commission affirms the Final ID's findings as to Complainants' other objective evidence of non-obviousness, including commercial success and Apple's alleged copying of Masimo's technology. *See* Final ID at 241. The Final ID found that this evidence does not support non-obviousness. *See id.*

3. Overall Conclusion as to Obviousness

Because the Commission alters the Final ID's findings as to the asserted claims of the '745 patent regarding secondary considerations, the Commission evaluates anew (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between

the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness.

Like the Final ID, the Commission finds, regarding claims 9 and 27 in view of the Apple Watch Series 0, that the prior art does not teach or suggest elements [1B], [1D], and [9] of claim 9 or elements [20B] and [20D] of claim 27. *See* Final ID at 212–14, 215–16, 218–20, 221, 222. And like the Final ID, regarding claims 9, 18, and 27 and combinations based on Iwamiya, the Commission finds that the prior art does not teach or suggest element [9] of claim 9, element [18] of claim 18, and element [27] of claim 27. *See id.* at 228–31, 235–36, 239–40. Regarding claims 9 and 18, the objective evidence of skepticism and failure of others regarding implementing wrist-based pulse oximetry weighs in favor of a finding of non-obviousness. Thus, in view of these underlying findings, taken as a whole, the Commission concludes that Apple has not shown that any of these claims are invalid by clear and convincing evidence. Last, we note that the Commission's conclusion would remain the same even if the objective evidence of skepticism and failure of others regarding implementing wrist-based pulse oximetry was not considered.

D. Written Description Support of Claim 28 of the '502 Patent and Claim 12 of the '648 Patent

The Final ID found that claim 28 of the '502 patent is invalid for lacking written description support as to elements [28A] and [28B] and also found that claim 12 of the '648 patent is invalid for lacking written description support as to elements [8A] and [8B], from which claim 12 depends. *E.g.*, Final ID at 336. The Commission reviewed this finding and requested briefing from the parties. *See* 88 Fed. Reg. at 32244. On review, the Commission reverses the Final ID for the reasoning provided below. In view of this conclusion and the Commission's

other conclusions herein, the Commission finds that Complainants have shown that Apple violated section 337 as to claims 22 and 28 of the '502 patent and claim 12 of the '648 patent, in addition to claims 24 and 30 of the '648 patent.

1. The Applicable Law

35 U.S.C. § 112 declares that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . ." 35 U.S.C. § 112. "[T]his statutory language mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004).

To comply with the written description requirement, a patent applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention." *Vas-Cath*, 935 F.2d at 1563–64 (emphasis omitted). The test for written description "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "[T]he applicant [for a patent] may employ 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" *In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009) (citing *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996)); *see also Enzo Biochem*, 323 F.3d at

964 (declaring that the written description may also be met by other "sufficiently detailed, relevant identifying characteristics," such as "physical and/or chemical prope1iies, functional characteristics when coupled with a known or disclosed con-elation between function and structure, or some combination of such characteristics") (emphasis omitted)). Compliance with the written description requirement is a question of fact, and in order to overcome the presumption of validity, a party must set forth clear and convincing evidence. *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.,* 636 F.3d 1341, 1347 (Fed. Cir. 2011).

2. **The Final** ID

As noted above, the Final ID concluded that claim 28 of the '502 patent is invalid for lacking written description suppo1i as to elements [28A] and [28B] and that claim 12 of the '648 patent is invalid for lacking written description suppo1i as to elements [8A] and [8B]. *See* Final ID at 156-70. As shown in the table below, these pairs of claim limitations require two separate sets of LEDs, each with an LED "configured to emit light at a first wavelength" and an LED "configured to emit light at a second wavelength."

Elements [28A] and [28B] of Claim 28 of the '502 Patent	
[28A]	a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
[28B]	a second set of LEDs spaced apa1i from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
Elements [SA] and [SB] of Claim 12 of the '648 Patent	
[SA]	a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
[SB]	a second set of LEDs spaced apaii from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

Before the ALJ, Apple argued that the disputed limitations lack written description support because the specifications fail to disclose separate sets of LEDs emitting at the same "first wavelength" and the same "second wavelength." *E.g.*, RPHBr. at 151–52; RPHBr. (Reply) at 75. Apple relied on the testimony of its expert witness, Dr. Warren, who testified that there was no support for these limitations. *See* Tr. (Warren) at 1247:13–17.

In reply, Complainants argued that Dr. Warren's testimony was conclusory and therefore insufficient for Apple to show invalidity by clear and convincing evidence. *E.g.*, CPHBr. at 179. Complainants further argued that their expert, Dr. Madisetti, identified support for the disputed limitations. *See, e.g.*, *id.* (citing Tr. (Madisetti) at 1349:7–1350:3); Final ID at 163. Complainants also relied on the specification, pointing to the two emitters (each having item number "104") depicted in Figures 7A and 7B, as well as, for example, the related disclosure that "the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." *See, e.g.*, CPHBr. at 179 (citing JX-0001 ('501 patent[36]) at 12:9–12, Fig. 7A, Fig. 7B). Figure 7B is reproduced below:

[36] As noted above, the '501, '502, and '648 patents share a common specification. The parties agree that citations to the '501 patent are also applicable to the '502 and '648 patents.

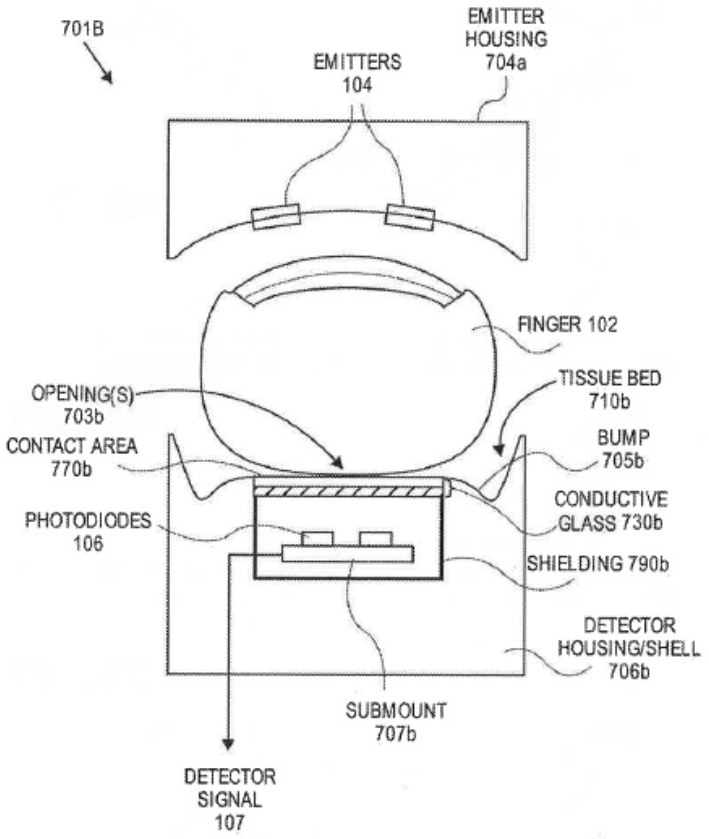

FIG. 7B

JX-0001 ('501 patent) at FIG. 7B. Figure 7A is largely identical to Figure 7B, with the most notable and relevant difference being that, in Figure 7A, the "emitters 104" are indicated as "LEDs 104." Complainants also cited other portions of the specification. *See, e.g.*, CPHBr. at 179–80 (citing JX-0001 ('501 patent) at 9:60–63, 12:13–25, 13:16–21, 21:51–54, 33:30–38, 38:8–22); Final ID at 163.

The Final ID agreed with Apple, concluding that the claim language at issue requires two different matching pairs of wavelengths between the two sets of LEDs. *See* Final ID at 163–65. In other words, the first wavelength of an LED in the first set of LEDs must match the first wavelength of an LED in the second set of LEDs, and the second wavelength of an LED in the first set of LEDs must match the second wavelength of an LED in the second set of LEDs. *See*

id.[37] The Final ID next found that there is no such disclosure in the specifications of the Poeze patents. *See id.* The Final ID acknowledged that, "[w]hen describing emitters that are capable of emitting visible and near-infrared optical radiation, the specification describes two different wavelengths, three different wavelengths, or up to eight different wavelengths," but then found that the "specification does not describe any two LEDs having the same wavelength." *Id.* at 164.

3. Complainants' Petition

In their petition for review, Complainants argued that the Final ID "failed to acknowledge that the presumption of validity carries with it a presumption that the specification has an adequate written description as required by 35 U.S.C. § 112." CPet. at 34. Complainants also argued that the Federal Circuit has repeatedly held that conclusory expert opinion testimony cannot overcome this presumption and the associated burden of "clear and convincing evidence." *See id.* at 34–35 (citing, *inter alia*, *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1338–39 (Fed. Cir. 2016); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004)). According to Complainants, the Final ID cited no evidence of what a person of ordinary skill in the art would understand from reading the specification, let alone any evidence supporting that a person of ordinary skill in the art would find no written description support for the disputed limitations. *Id*. at 37. Complainants added that the specification "discloses that emitter 104 can include 'sets of optical sources that are capable of emitting visible and near-infrared [light]'—*i.e.*, emitting light at a first wavelength and a second wavelength," and it teaches "exemplary LED sets." *Id.* (citing JX-0001 ('501 patent) at 12:9–12, 4:55–57, 26:32). Complainants further argued that the "specification provides additional examples where the emitter 104 includes sets

[37] Neither party contests this interpretation of the claim language, either in their petitions for review of the Final ID or in their briefing in response to the Commission's notice of review.

of LEDs to emit light at two or more different wavelengths," including that "emitter 104 can emit [light] at or about 1610 nm, about 1640 nm, *and* about 1665 nm." *Id.* (citing JX-0001 ('501 patent) at 12:38–40, 12:64–13:1, 13:5–7) (emphasis added). Thus, according to Complainants, the specification "discloses an emitter 104 including a set of LEDs that emits light at a first wavelength and a second wavelength." *Id.* (emphasis omitted).

Complainants further argued that Figure 7B shows two such emitters, each labeled 104, and that USPTO rules provide a presumption that each emitter set 104 is identical. CPet. at 38 (citing 37 C.F.R. § 1.84(p)(4)[38]). Complainants then concluded that, by virtue of Figure 7B, the specification "discloses that the first and second wavelengths of the set of LEDs of one emitter 104 are the same as (*i.e.*, match) the first and second wavelengths of the corresponding set of LEDs of the other emitter 104." *Id.* at 39.

4. Apple's Response

In reply, Apple argued that the Final ID properly acknowledged the presumption of validity and properly found that the claim language "does not merely require that there be two sets of LEDs, each emitting light at two different wavelengths," but instead also "requires matching wavelengths in each set of LEDs." RResp. (Summary) at 4. Apple further argued that Dr. Warren's testimony supports that the claims lack written description, and here, "no more elaboration was required." *See* RResp. at 30–31. According to Apple, the only relevant issue was whether the specification disclosed the recited feature, and "there was nothing more that Dr. Warren could have said because, at the time he presented his testimony, Complainants had not

[38] 37 C.F.R. § 1.84(p)(4) recites: "The same part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts."

even challenged the point that he confirmed in his testimony—namely, that there was no written description support for two sets of LEDs each with LEDs emitting at the same 'first wavelength' and 'second wavelength.'" *Id.* at 30–32 (citing, *inter alia*, Tr. (Warren) at 1247:13–17; CPreHBr. at 126;[39] CPHBr. at 179–80).

Apple further argued that the Final ID relied on more than just Dr. Warren's testimony by walking "through the portions of the specification that Complainants had identified in their post-hearing briefs" and confirming, based on that analysis, and "consistent with Dr. Warren's testimony, that none [of those cited portions] discloses two sets of LEDs each with LEDs emitting at the same 'first wavelength' and 'second wavelength.'" *Id.* at 32 (citing Final ID at 163–64); *see also id.* at 32–35. Apple also asserted that, in Complainants' petition for review of the Final ID, Complainants "offer[ed a] lengthy, entirely new analysis of the Poeze specification," but this new analysis was allegedly waived for not being presented to the ALJ. *Id.* at 32 (citing, *inter alia*, CPreHBr. at 123–27; CPHBr. at 175–80; Order No. 4 (Ground Rules), at Ground Rules 9.2 and 13.1; *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012)); *see also id.* at 32–35.

5. Analysis

The Commission has determined to reverse the Final ID and conclude that Apple did not carry its burden of proving, by clear and convincing evidence, that claim 28 of the '502 patent and claim 12 of the '648 patent are invalid for lacking written description support. As noted

[39] The Commission notes that, contrary to Apple's argument, Complainants' pre-hearing brief declared: "A [person of ordinary skill in the art] would . . . understand from the disclosure of emitter 'sets' that *corresponding LEDs in each set have the same wavelength* to allow the sensor to collect data from multiple measurement sites with multiple light paths." CPreHBr. at 126 (emphasis added).

above, because patent claims are presumed valid under 35 U.S.C. § 282, a party challenging the validity of a patent(s), including for lack of written description, must demonstrate by clear and convincing evidence that challenged patents are invalid. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011) ("To overcome the presumption of validity of patents, the accused must show that the claims lack a written description by clear and convincing evidence."). The Commission finds that Apple did not meet its burden of proof because it relied on conclusory expert witness testimony and then on attorney argument alone to explain why Complainants' citations to the specification did not provide written description support, *see, e.g.*, RPHBr. (Reply) at 75, and Complainants' citations to the specification and its expert witness's testimony tend to show that the disputed limitations have written description support.

As an initial matter, the Commission agrees with Complainants that Apple's expert's testimony is conclusory. Dr. Warren simply stated:

> Q..... Have you identified any discussion in the Poeze specification of the use of multiple sets of LEDs each with LEDs emitting at a first wavelength and a second wavelength?
>
> A. I have not found one, no.

Tr. (Warren) at 1247:14–17. While, as Apple points out, reliance on expert testimony is not always necessary to find a claim invalid for written description,[40] in this case, Apple's expert witness testimony is conclusory, and, as discussed below, it is not clear from the face of the patents that the disputed claims lack written description. Thus, the expert testimony here is

[40] *See* RBr. at 30–31 (citing, *inter alia*, *Centocor*, 636 F.3d 1341, 1347; *Certain Beverage Brewing Capsules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-929, Comm'n Op., 2016 WL 9751230, at *18 (Apr. 5, 2016), *aff'd by Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315 (Fed. Cir. 2017)).

distinguishable from that in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1325 (Fed. Cir. 2000), relied upon by the Final ID (*see* Final ID at 164–65), where the trial judge relied on extensive expert testimony and other prior art documents.

Turning to the evidence cited by Complainants to the ALJ, Figures 7A and 7B show two emitters or two LEDs, each labeled 104:

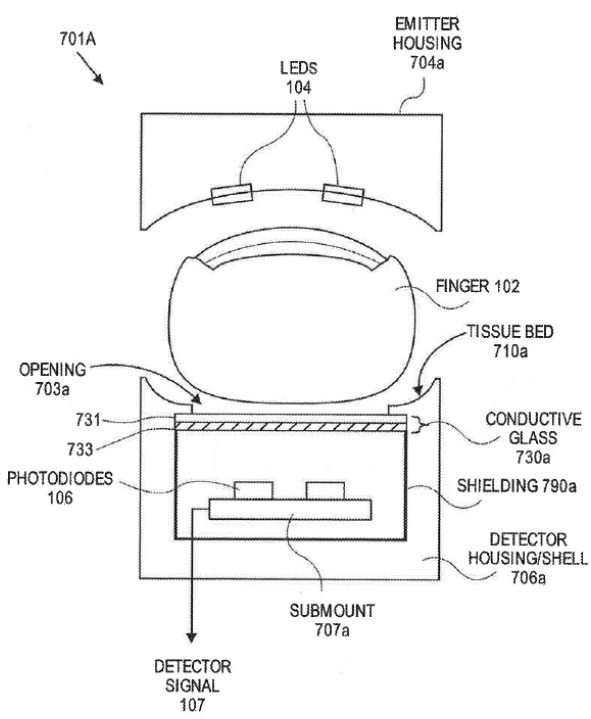

FIG. 7A

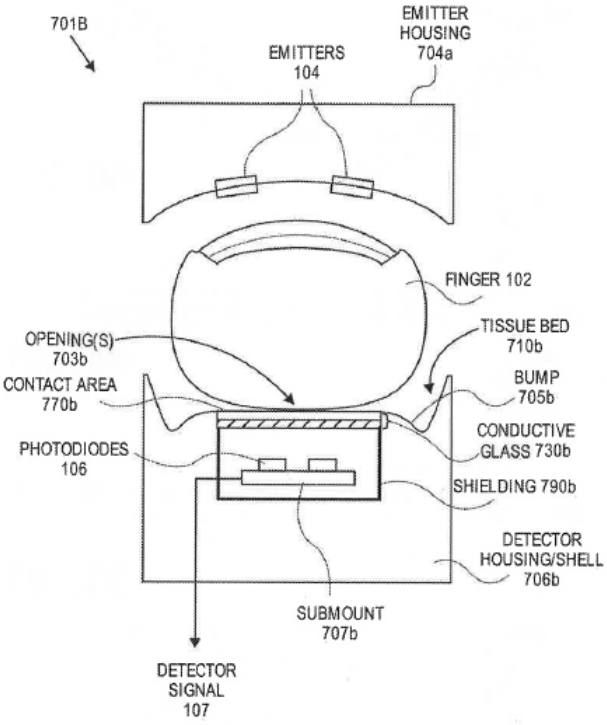

FIG. 7B

See CPHBr. at 179; *E.g.*, JX-0001 ('501 patent) at Figs. 7A, 7B. The fact that the LEDs and the emitters share the number (104) across the two figures, suggests that they are the same (*i.e.*, both can include sets of LEDs). *See, e.g.*, JX-0001 ('501 patent) at 13:16–21 ("[T]he emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source."). Even more than that, within Figure 7A, the two LEDs share the same label "LEDs 104," and within Figure 7B, the two

emitters share the same label "Emitters 104." This suggests that the two LEDs in Figure 7A are the same, and the two emitters in Figure 7B are the same.[41]

The specifications further explain that: "In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." *E.g.*, JX-0001 ('501 patent) at 12:9–12; *see also, e.g.*, *id.* at 9:60–63, 13:16–21; Tr. (Madisetti) at 1349:7–1350:3. If the two sets of LEDs or the two emitters having sets of optical sources are the same, then they must emit the same visible and near-infrared optical radiation, *i.e.*, at the same two respective wavelengths. At a minimum, the specifications do not clearly and convincingly show that these respective wavelengths of visible and near-infrared optical radiation are different between the identically-labelled LEDs or optical emitters.

Apple also responds that "'visible and near-infrared light' are not specific wavelengths," and thus the sets of LEDs do not include matching pairs of wavelengths. *See* RBr. at 52–53. The Commission agrees with Apple that "visible light" and "near-infrared light" both refer to ranges of wavelengths. However, because Figures 7A and 7B each show two sets of the same LEDs or optical emitters, the Commission finds that the LEDs/optical emitters in the first set would emit the same light as the LEDs/optical emitters in the second set. The fact that this disclosure *could be* interpreted by a skilled artisan, as Apple suggests, to encompass situations where the first LED set emits visible light at one wavelength and near-infrared at a second wavelength, and the second LED set emits visible light at a third wavelength and near-infrared

[41] The Commission's conclusion is based on the specifications themselves, not on 37 C.F.R. § 1.84(p)(4), which Complainants cited for the first time in their petition for review of the ALJ's Final ID. Thus, while the parties contest whether a waiver by Complainants prevents the Commission from relying on that rule, those arguments are moot because, in view of the specifications, the Commission need not and does not rely on that rule.

light at a fourth wavelength, does not mean that this is how a skilled artisan would understand the disclosure, especially when there is no testimony to this effect. Again, at a minimum, the specifications do not clearly and convincingly show that these respective wavelengths of visible and near-infrared optical radiation are not the same between the sets of LEDs/optical emitters.

Thus, in view of Complainants' above-discussed citations to the specification and Apple's conclusory expert testimony, the Commission concludes that Apple has not met its burden of proof to show by clear and convincing evidence that Complainants did not convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicants were in possession of the claimed inventions.

In their petition for review and in their briefing to the Commission, Complainants cite additional passages from the specification that, although not necessary to sustain the Commission's conclusion, further support it. CBr. at 42–48 (citing JX-0001 ('501 patent) at 4:55–57, 9:4–6, 12:5–9, 12:26–32, 12:38–40, 12:64–13:6, 13:21–25, 29:19–22, 33:26–36). Apple alleges that Complainants waived reliance on these passages because Complainants cite these passages for the first time in their petition for review. The Commission notes, however, that these passages are intrinsic evidence within the four corners of the patent and they merely reinforce Complainants' general argument to the ALJ. *See, e.g.*, Order No. 4 (Ground Rules), EDIS Doc. ID 752396, at Ground Rule 13.1 (Initial Post-hearing Briefs; Filing and Content) (declaring only an *issue* is waived when that *issue* is not "included in the pre-hearing brief"). Thus, under these circumstances, the Commission declines to find Complainants' reliance on this evidence waived.

Complainants' newly-cited passages of the specification show that, in Figure 7B, each emitter 104 includes sets of LEDs that can emit light "at or about 1610 nm, about 1640 nm, *and*

about 1665 nm." JX-0001 ('501 patent) at 12:38–40 (emphasis added); *see also, e.g.*, CBr. at 42–48. Complainants additionally rely on JX-0001 ('501 patent) at 4:55–57, 9:4–6, 12:5–9, 12:26–32, 12:38–40, 12:64–13:6, 13:21–25, 29:19–22, 33:26–36. Complainants reason that Figure 7B shows two emitters, so each emitter 104 would have an LED with *each* of those three wavelengths, *i.e.*, at or about 1610 nm, at or about 1640 nm, *and* at or about 1665 nm, JX-0001 ('501 patent) at 12:5–9, 12:38–40, and thus the two emitters include at least matching pairs of wavelengths.[42] *Id.* at 43–44. This evidence further confirms the Commission's conclusion that Apple has not shown by clear and convincing evidence that the relevant claims are invalid for lacking written description support.[43]

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[42] Regarding the wavelengths disclosed in these passages, Apple argues that the passages relate to measuring "analytes like glucose," not "oxygen" or "oxygen saturation," as the claims require, and thus those teachings cannot provide written description support here. *See* RBr. at 51–52 (citing JX-0001 ('501 patent) at 12:26–44). The Commission, however, agrees with Complainants that the specific wavelengths mentioned in the specification are "irrelevant because specific wavelengths are not claimed," as the "claims merely recite that the two wavelengths used in the first set of LEDs—whatever they may be—are the same wavelengths used in the second set." CBr. (Reply) at 26. Other portions of the specification, including those cited by Complainants, recite that the emitters 104 can have other matching wavelengths. JX-0001 ('501 patent) at 12:60–13:7 ("Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements.").

[43] Chairman Johanson would not reverse the ALJ's well-reasoned determination that claim 28 of the '502 patent and claim 12 of the '648 patent are invalid for lacking written description support.

The written description requirement "is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Ariad*, 598 F.3d at 1354. While the requirement does not demand any particular form of disclosure, "a description that merely renders the invention obvious does not satisfy the requirement." *Id.* at 1352.

In finding support for disputed claims in the original specification, the majority relies heavily on the specification's teaching that "[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation," JX-0002 ('502 patent) at col. 12:9–12, and Figures 7A and 7B. The majority, noting that Figure 7B has two structures designated 104, concludes that "[i]f the two sets of LEDs or the two emitters

E. Claim Construction and Infringement Regarding the '745 Patent

The Final ID found that the Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent. *E.g.*, Final ID at 336. The Commission determined to review this finding of the Final ID. *See* 88 Fed. Reg. at 32244. On review, the Commission has determined to affirm the Final ID without modification, thus adopting the Final ID's analysis.

F. The Domestic Industry Issues Under Review—The Poeze Patents and the '745 Patent

The Final ID found that the technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, and claim 18 of the '745 patent, and that the economic prong of the domestic industry requirement has been satisfied with respect to the '501, '502, '648, and '745 patents.

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having sets of optical sources are the same, then they must emit the same visible and near-infrared optical radiation." There is, however, no teaching that the emitters are the same. *See* Final ID at 164 ("there is no disclosure of two separate sets of LEDs using the same wavelengths in each set"). Rather, the specification and figures use "emitters" as a broad term for any light source of any frequency. Indeed, element 104 is used inconsistently in the figures relied upon by the majority. *Compare* Figure 7A with 7B.

Moreover, both Figures 7A and 7B depict embodiments that differ meaningfully from that of claim 28 of the '502 patent (which requires four photodiodes with aligned openings) or claim 12 of the '648 patent (similar limitations). This suggests a failure to describe each claim as an "integrated whole." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) ("Taking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the 2000 application in vain for the disclosure of even a single species that falls within the claims.").

The majority further relies on Respondents' expert testimony being "conclusory." This is not persuasive. Caselaw is plain that no expert testimony is necessary to show a failure to comply with the written description requirement. *See, e.g.*, *Centocor*, 636 F.3d at 1347. Further, Complainants' expert testimony lacks any discussion of the import of the disclosure found in column 12 relied on by the majority. *See* Tr. (Madisetti) at 1350:22–1352:4.

Considered as a whole, the evidence suggests that these late added claims (added by amendment years after the original priority date) reach beyond any disclosure fairly described by the specification and figures. Accordingly, Chairman Johanson would affirm the ALJ's determination that these claims are not fully supported by the original disclosure.

E.g., Final ID at 336. The Commission detennined to review these findings of the Final ID. *See* 88 Fed. Reg. at 32244.

On review, the Commission has detennined to take no position regarding the Final !D's findings as to (1) whether post-Complaint evidence can be considered in satisfying the domestic industry requirement in this case with respect to the '501, '502, '648, and '745 patents; and (2) whether Complainants had shown a domestic industry in the process of being established. *See* 19 U.S.C. § 1337(a)(2); *Beloit,* 742 F.2d at 1423; *see also, e.g.,* Final ID at *56-59,,* 62 n.16, 85-87, 209,302 n.116, 319,324.

The Commission affnms, however, the Final !D's finding that Complainants have shown the existence of a domestic industry by way of significant employment of labor with respect to Masimo's investments in research and development for the Masimo Watch, but with the following modified reasoning. Final ID at 317-18.

The Final ID found that Complainants' employment of labor was significant, in pa.ii, because it involved I employees [redacted] full-time equivalents) representing over-percent of Masimo's research and development engineers. Final ID at 317. The Commission additionally finds that Complainants' employment of labor is quantitatively significant because the identified employment of labor is [redacted] percent domestic. As the Final ID found,- research and development of the Masimo Watch has occurred in the United States. *Id.* (citing CPHBr. at 307); *see also* Tr. (Kiani[44]) at 321:23-322:5 (testifying that reseai·ch and development occuned in Ilvine, Califomia).[45]

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[44] Joe Kiani is the chai1man and chief executive officer of Masimo and Cercacor. *E.g.,* Final ID at 5.

[45] The Final ID recognized that Complainants presented evidence regarding approximately-in payments to ce1iain third-paiiy fnms for "design" work on the

The Commission finds that the fact that research and development of the Masimo Watch occurs [redacted] percent in the United States, combined with the qualitative significance of research and development to the Masimo Watch (Final ID at 318), shows that Complainants' employment of labor is significant. *See* Final ID at 317 (citing *Gas Spring Nailer Prods. & Components Thereof,* Inv. No. 337-TA-1082, Comm'n Op. at 83 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [domestic industiy products] occurs in the United States"), *vacated and remanded on other grounds, Kyocera Senco Indus. Tools v. Int'l Trade Comm'n,* 22 F.4th 1369 (Fed. Cir. 2022)).

The Commission othe1wise affnms the Final !D's domestic industiy analysis as to the '501, '502, '648, and '745 patents, including the Final !D's finding that Complainants' plant and equipment investments were not significant. *See* Final ID at 315. Because the Final ID found that Complainants satisfied the domestic industiy requirement as to these patents based only on pre-Complaint investments, the Commission dete1mines that Complainants have satisfied the domestic industiy requirement as to the '501, '502, '648, and '745 patents based on an "existing" domestic industiy. *See* 19 U.S.C. § 1337(a)(3).

Masimo Watch *(see* CBr. at 26), but did not credit that evidence towards a domestic industiy because it was unclear if those fnms perfo1med design work in the United States. Final ID at 313-14. However, even if nts were directed to foreign labor, they are an order of magnitude smaller than the- employment of research and development labor at Masimo's U.S. facilities. *Id.* (finding that "these ex enditures are relatively small in comparison to Masimo's R&D expenditures"). Thus, the of Complainants' employment of labor is domestic and Complainants' domestic industiy is therefore significant.

V. REMEDY, THE PUBLIC INTEREST, AND BONDING

The Commission has determined to issue an LEO and a CDO. Both remedial orders include a service, repair, and replacement exemption (discussed below in the context of the public interest), and will go into effect, without delay, at the end of the period of Presidential review. The Commission has concluded that the public interest does not counsel against providing Complainants this remedy. The Commission has also determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

A. Remedy

The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. US. Int'1 Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

1. Limited Exclusion Order

As discussed below, the Commission has determined to issue an LEO directed to covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. The LEO includes the standard certification provision; includes a service, repair, and replacement exemption for infringing articles purchased prior to the expiration of the period of Presidential review; and is to go into effect without delay.

a. The Applicable Law

Section 337(d)(1) provides that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1).

b. The RD

Before the ALJ, Complainants requested that the Commission issue an LEO to remedy Apple's section 337 violation. *E.g.*, RD at 1; CPHBr. at 310–11. For its part, Apple argued that any LEO should include an exemption for "the continued service, repair, or replacement of previously purchased products, including software maintenance and updates." *E.g.*, RD at 1; RPHBr. at 279. Apple further requested that any LEO include the standard certification provision and be no broader in scope than the scope of the investigation. *E.g.*, RD at 1–2; RPHBr. at 175, 279.

The RD recommended that any LEO be directed to Apple's importation of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof. RD at 2 (citing 86 Fed. Reg. at 46275 (defining scope of investigation)). The RD additionally declared that the record at the time did not include evidence to support an exemption for service, repair, or replacement. *Id.* at 2–3. The ALJ further recommended that any LEO include the standard certification provision. *Id.* at 3–4 (citing *Certain Composite Aerogel Insulation Materials & Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm'n Op. at 62–63, EDIS Doc. ID 637154 (Feb. 22, 2018); RPHBr. at 279). In doing so, the RD properly recognized that any non-adjudicated redesigns would not be subject to certification. *Id.* at 4 (citing *Certain Automated Teller Machines, ATM Modules, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-972, Comm'n Op. at 26–27 and n.18, EDIS Doc. ID 613988 (June 12, 2017)).

c. The Parties' Arguments

In their briefing to the Commission, Complainants again request that the Commission issue an LEO. *See* CBr. at 87–88. Complainants accept the RD's recommendation that the LEO include a certification provision. *See id.* (citing RD at 4). Complainants further declare that the

LEO should not include any exemption for a service, repair, or replacement for the reasons it discusses related to the public interest, discussed below. *See id.* at 88; *see also* CBr. (Reply) at 42–43. Complainants additionally argue that the LEO should state that no infringing articles should be allowed to be imported for any purpose, including the importation of any unreleased products for "engineering validation testing," "design validation testing," or "product validation testing" prior to commercial launch. CBr. at 88. Complainants further argue that the Commission should reject Apple's request for an enforcement delay. *See* CBr. (Reply) at 40–41.

Apple argues that, for public interest reasons (discussed below), the Commission should decline to issue a remedy, or at least suspend enforcement of any remedy for twelve months and/or include an exemption allowing for the service, repair, and replacement of customers' Apple Watches. *E.g.*, RBr. at 88–90, 67–72. Apple additionally declares that any LEO should contain the standard certification provision. *See id.* at 90–91. Apple further argues that Complainants' "proposed LEO and CDO fail to conform the orders with the scope of the Investigation as defined in the Notice of Investigation: 'wearable electronic devices with light-based pulse oximetry functionality and components thereof.'" *Id.* at RBr. (Reply) at 49 (quoting 86 Fed. Reg. at 46276) (citing *Certain Automated Mechanical Transmission Sys.*, Inv. No. 337-TA-503, Comm'n Op. at 4 (May 9, 2005)). Apple further points out Complainants' requested remedial orders improperly seek to cover "hardware and *software* components thereof." *Id.* (quoting CBr. at Appx. A, B) (Apple's emphasis). Regarding "software components," Apple argues that those, as "electronic transmissions," are outside the scope of the Commission's jurisdiction. *Id.* (citing *ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1286 (Fed. Cir. 2015)). Apple further addresses Complainants' assertion that any LEO should provide "that no infringing articles should be imported for any purpose." *Id.* at 50 (quoting CBr.

at 88). Apple declares that it is "unaware of any instance in which the Commission has included such additional language in the past, and Complainants offer no proper basis to do so in this case." *Id.*

d. Analysis

The Commission has determined to issue an LEO directed to covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. Consistent with standard practice, the Commission defines "covered products" in accordance with the plain language description of the accused products in the Complaint (*see* 19 C.F.R. § 210.10(b)(1)), which is "wearable electronic devices with light-based pulse oximetry functionality and components thereof." 86 Fed. Reg. at 46276. The Commission also agrees with Apple that the LEO (and CDO) should not cover "software components." *See* RBr. (Reply) at 49 (citing *ClearCorrect*, 810 F.3d at 1286 (Fed. Cir. 2015)); *see also, e.g.*, *Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, Inv. No. 337-TA-1266, Comm'n Op. at 50 n.33 (Jan. 20, 2023) ("Commission exclusion orders, however, do not extend to electronic transmissions.").

The issued LEO also includes the standard certification. Neither party has shown a valid basis for deviating from the Commission's standard practice. Complainants argue that the LEO should include language that "clarifies that Apple cannot use the certification procedure for redesigns that have not been adjudicated as non-infringing." *See* CBr. at 87. While the Commission declines to adopt that language as part of the Order itself, as the RD correctly recognized, the standard certification does not apply to redesigns that have not been adjudicated as non-infringing. *See* RD at 4 (citing *Automated Teller Machines*, Inv. No. 337-TA-972, Comm'n Op. at 26–27 (including n.18) ("The standard certification language does not apply to redesigns that have not been adjudicated as non-infringing." (Internal quotations removed))).

Should the Commission or U.S. Customs and Border Protection ("CBP") later determine that a redesigned article presented for adjudication does not infringe, the certification provision can operate to exempt those articles.

Complainants argue that the LEO should explicitly state that no infringing articles should be allowed to be imported "for any purpose." CBr. at 88. However, Complainants have shown no valid reason for why the Commission's LEO should include this non-standard language. Moreover, Complainants' request is inconsistent with section 337, which does not allow the Commission to bar, for example, products "imported by and for the use of the United States." 19 U.S.C. § 1337(l).

For the reasons discussed below in the context of the public interest,[46] the LEO includes a service, repair, and replacement exemption. *See infra* section V.B.4.a.iii. However, also for the reasons discussed below in the context of the public interest, the Commission denies Apple's request that the LEO be subject to a twelve-month delay.

2. Cease and Desist Order

As discussed below, the Commission has determined to issue a CDO directed to Apple and covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. The CDO includes a service, repair, and replacement exemption for

[46] Commissioner Kearns disagrees with the Commission majority's position that public interest is the sole statutory ground for exemptions from the scope of remedial orders. As he explained in *Certain Cloud-Connected Wood-Pellet Grills & Components Thereof*, Inv. No. 337-TA-1237 ("*Grills*") (joined by Commissioner Karpel), the Commission's reviewing court has stated that the Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Grills,* Comm'n Op. at 11–12 (including n.10) (May 24, 2022). Moreover, they observed that "the Commission has repeatedly indicated that it has granted warranty and repair exemptions 'when unopposed, in view of the public interest, or upon some showing of a need for service and repair.'" *Grills*, Comm'n Op. at 11 n.10.

infringing articles purchased prior to the expiration of the period of Presidential review, and the CDO is to go into effect without delay.

a. The Applicable Law

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for a violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, the respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.[47] *See, e.g.*, *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 4–6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, USITC Pub. No. 4405, Comm'n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22 (June 24, 2007)). Complainants bear the burden on this issue: "[a] complainant seeking a [CDO] must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order." *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 5 (citing *Certain Integrated Repeaters, Switches,*

[47] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations needs to be "commercially significant" in order to issue the CDO. *See, e.g.*, *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65 n.24 (Apr. 9, 2019); *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 6 n.2 (Feb. 1, 2017). In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO. *Id.*

Transceivers, & Prods. Containing Same, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm'n Op. at 27 (Aug. 16, 2002); H.R. REP. No. 100-40, at 160 (1987)).

b. The RD

Before the ALJ, Complainants sought a CDO based on evidence of Apple's significant inventory of Accused Products. *E.g.*, RD at 4 (citing CPHBr. at 311). For its part, Apple argued that any CDO should include service, repair, and replacement exemption that permits "the continued service, repair, or replacement of previously purchased products, including software maintenance and updates." *Id.* (quoting RPHBr. at 279).

The RD found that "[t]here is no dispute that Apple maintains a significant commercial inventory of Accused Products." *Id.* at 5 (citing CPHBr. at 311; CX-0128C at ¶ 5). The RD further found that there is also "evidence that Apple has significant domestic operations, because Apple is headquartered in California and has over 75,000 U.S. employees." *Id.* (citing RStmt.). Thus, the RD recommended the issuance of a CDO against Apple. *Id.*

c. The Parties' Arguments

Complainants request that the Commission issue a CDO directed to Apple. *See* CBr. at 87–88. The parties make the same arguments as to the scope of the CDO that they made for the LEO. *See id.* at 88; RBr. at 88–90, 67–72. Apple does not dispute the RD's findings that it maintains a significant commercial inventory of Accused Products and has significant domestic operations. *See generally* RBr.; RBr. (Reply); *see also* RD at 5.

d. Analysis

The Commission has determined to issue a CDO directed to Apple and covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648

patent.[48] The Commission adopts the undisputed findings in the RD that Apple maintains a commercially significant inventory of Accused Products and has significant domestic operations. RD at 5; *see also generally* RBr. (not disputing that it maintains a commercially significant inventory or has significant domestic operations); RBr. (Reply) (same). The issued CDO directs Apple to cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of wearable electronic devices with light-based pulse oximetry functionality and components thereof that infringe claims 28 of the '502 patent or any of claims 12, 24, and 30 of the '648 patent. The language of the CDO is consistent with the Commission's standard practice of using the plain language description of the accused products in the Complaint as the definition of "covered products." *See* 19 C.F.R. § 210.10(b)(1). The scope of the CDO, like the LEO, is discussed below in the context of the public interest.

B. Public Interest

To prevent any harm from the remedial orders to the public health and welfare and to United States consumers, the Commission's LEO and CDO each include a service, repair, and replacement exemption. In view of this exemption, the public interest factors do not counsel against providing Complainants a remedy. Apple has not shown any reason why the Commission should delay the enforcement of its remedy.

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[48] Commissioner Schmidtlein agrees that a CDO should issue directed to Respondent Apple, but she differs from the majority with respect to the basis for that determination. *See supra* note 47 ("[T]he presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO.").

1. The Applicable Law

Section 337 requires that the Commission, upon finding a violation of section 337, issue an LEO "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(l). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g.*, *Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm'n Op. at 1–2, 23–25 (Oct. 1984) (finding that the public interest warranted denying complainant's requested relief). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third-party consumers to transition to non-infringing products. *E.g.*, *Certain Microfluidic Devices*, Inv. No. 337-TA-1068 Comm'n Op. at 1, 22–48, 53–54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 32–33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, comm'n Op. at 150–51 (Oct. 2011) (grandfathering certain products); *Certain*

Personal Data & Mobile Comm'n Devices & Related Software, 337-TA-710, USITC Pub. No. 4331, Comm'n Op., at 72–73, 80–81 (June 2012) (delaying imposition of remedy).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. *See* 19 U.S.C. § 1337(d)(l), (f)(l). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. *See* 19 U.S.C. § 1337(d)(l) & (f)(l).

2. Non-Party Comments on the Public Interest

The Commission's solicitation of public interest comments following the ALJ's RD (88 Fed. Reg. 6312, 6312–13 (Jan. 31, 2023)) resulted in numerous submissions on the public interest from non-parties, including:

(1) Public Interest Comments of David Albert, EDIS Doc. ID 790883 (Feb. 22, 2023) ("Albert Stmt.");

(2) Public Interest Statement of the Alliance for U.S. Startups and Inventors for Jobs, EDIS Doc. ID 791674 (Mar. 3, 2023) ("Alliance for U.S. Startups Stmt.");

(3) Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party, EDIS Doc. ID 791476 (Mar. 1, 2023) ("AHA Stmt.");

(4) Public Interest Letter from the Honorable Ken Buck, Henry C. Johnson, Jr., and Katie Porter, EDIS Doc. ID 791047 (Feb. 23, 2023) ("Buck Stmt.");

(5) Public Interest Comments from C4IP, EDIS Doc. ID 791567 (Mar. 2, 2023) ("C4IP Stmt.");

(6) Public Interest Comments of Bill Carpou from Octane, EDIS Doc. ID 790962 (Feb. 23, 2023) ("Carpou Stmt.);

(7) Statement of Third Party Computer and Communications Industry Association in Response to the Commission's January 31, 2023, Notice of Request for Statements on the Public Interest, EDIS Doc. ID 791054 (Feb. 23, 2023) ("CCIA Stmt.");

(8) Public Interest Statement of Consumer Federation of America, EDIS Doc. ID 791163 (Feb. 27 2023) ("CFA Stmt.");

(9) Public Comments from California Life Sciences, EDIS Doc. ID 791012 (Feb. 23, 2023) ("CLS Stmt.");

(10) Letter of Support from Cure HHT, EDIS Doc. ID 790394 (Feb. 15, 2023) ("Cure HHT Stmt.");

(11) Public Interest Statement of David Dinielli and Michael Enseki-Frank, EDIS Doc. ID 791686 (Mar. 3, 2023) ("Dinielli Stmt.");

(12) Public Interest Statement of Ryan Drant from Questa Capital, EDIS Doc. ID 790991 (Feb. 23, 2023) ("Drant Stmt.");

(13) Public Interest Statement of Non-Party Mitchell Goldstein, M.D., EDIS Doc. ID 791179 (Feb. 27, 2023) ("Goldstein Stmt.");

(14) Public Interest Comments from Innovation Alliance, EDIS Doc. ID 791048 (Feb. 23, 2023) ("Innovation Alliance Stmt.");

(15) Public Interest Statement of Josh Malone, EDIS Doc. ID 790787 (Feb. 21, 2023) ("Malone Stmt.");

(16) Christopher McCarthy Public Interest Statement Points Supporting Masimo, EDIS Doc. ID 789080 (Feb. 1, 2023) ("McCarthy Stmt.");

(17) Public Interest Statement of Non-Party of Medical Device Manufacturers Association (MDMA), EDIS Doc. ID 791167 (Feb. 27, 2023) ("MDMA Stmt.");

(18) Public Interest Statement of Richard Milani, M.D., EDIS Doc. ID 791665 (Mar. 2, 2023) ("Milani Stmt.");

(19) Statement of Third Party Law Professors Adam Mossof and Kristen Osenga in Response to the Commission's Notice of Request for Statements on the Public Interest and Reply to Respondent's Statement of February 22, 2023, EDIS Doc. ID 791069 (Feb. 23, 2023) ("Mossof Stmt.");

(20) National Jewish Health Support for the Apple Watch for Use in Tracking Physiologic Features in Medical Patients, EDIS Doc. ID 790602 (Feb. 17, 2023) ("NJH Stmt.," letter authored by Russell Bowler, M.D., Ph.D.);

(21) Cynthia Persaud Comments for Inv. 337-1276, EDIS Doc. ID 789338 (Feb. 3, 2023) ("Persaud Stmt.");

(22) Public Interest Statement of Non-Party Peter Pronovost, M.D., EDIS Doc. ID 791162 (Feb. 27, 2023) ("Pronovost Stmt.");

(23) Public Interest Statement of Non-Party Patient Safety Movement Foundation, EDIS Doc. ID 791175 (Feb. 27, 2023) ("PSMF Stmt.," letter authored by Dr. Michael Ramsay);

(24) Stanford University Medical Center Letter in Support of Apple Watch, EDIS Doc. ID 791060 (Feb. 23, 2023) ("Stanford Stmt.," letter authored by Stephen Ruoss, MD);

(25) StopAFib.org Letter of Support, EDIS Doc. ID 790642 (Feb. 21, 2023) ("StopAFib.org Stmt.");

(26) University of Michigan Health Letter of Support for Apple Watch, EDIS Doc. ID 790641 (Feb. 21, 2023) ("Univ. of Mich. Stmt.," letter authored by Jessica R. Golbus MD, MS);

(27) Public Interest Comments of US Inventor, Inc., EDIS Doc. ID 791041 (Feb. 23, 2023) ("US Inventor Stmt.");

(28) Dr. Robert M. Watcher Letter in Support of Apple and Public Interest, EDIS Doc. ID 790510 (Feb. 16, 2023) ("Wachter Stmt.");

(29) Public Interest Statement of Kevin R. Ward, MD, EDIS Doc. ID 790884 (Feb. 22, 2023) ("Ward Stmt.");

(30) Comments from Dr. Adam Waddell, MD, EDIS Doc. ID 789029 (Jan. 31, 2023) ("Waddell Stmt.");

(31) Public Interest Statement of Non-Party Bobby Yazdani, EDIS Doc. ID 791177 (Feb. 27, 2023) ("Yazdani Stmt.").

The Commission's notice of review (88 Fed. Reg. at 32243–46 (May 19, 2023)) also resulted in several submissions from third parties:

(1) Public Interest Comments from Council for Innovation Promotion (C4IP), EDIS Doc. ID 797854 (June 5, 2023) ("C4IP Comments");

(2) Public Interest Comments from Hugh Calkins, M.D., EDIS Doc. ID 797827 (June 5, 2023) ("Calkins Comments");

(3) Public Interest Comments from Nelson Freimer, M.D., EDIS Doc. ID 797817 (June 5, 2023) ("Freimer Comments");

(4) Public Interest Comments from Calum A. MacRae, MD, PhD, EDIS Doc. ID 797826 (June 5, 2023) ("MacRae Comments");

(5) Public Interest Comments from Rod S. Passman, M.D., M.S.C.E., EDIS Doc. ID 797813 (June 5, 2023) ("Passman Comments");

(6) Comments on Public Interest from Leslie A. Saxon, M.D., EDIS Doc. ID 797811 (June 5, 2023) ("Saxon Comments");

(7) Public Interest Comments from Professors Francisco J. Valero-Cuevas, PhD and Najmedin Meshkati, PhD, CPE, EDIS Doc. ID 798257 (June 12, 2023) ("Valero-Cuevas Comments").

The Commission has considered all of these submissions in making its final determination.

3. Whether Apple is Collaterally Estopped from Arguing the Merits of the Public Interest

As a preliminary matter, Complainants allege that Apple is collaterally estopped from arguing the merits of its public interest arguments. *E.g.*, CBr. at 56–57. As discussed below, the Commission disagrees.

a. The Parties' Arguments

Complainants argue that Apple should be estopped from arguing the merits of the public interest, reasoning that Apple already presented its arguments to the Commission in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, where the Commission concluded that the public interest did not weigh against excluding the infringing Apple Watches.[49] *See* CBr. at 56–57. Complainants argue that the Commission has previously applied collateral estoppel when: (1) the issue decided in the prior litigation is identical to that before the tribunal; (2) the issue was actually litigated in the prior proceeding; (3) the resolution of the issue in the prior litigation was necessary to its resulting judgment; and (4) the party against whom collateral estoppel is

[49] In that investigation, the complainant (AliveCor, Inc.) accused the Apple Watch Series 4, 5, 6, and 7. *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 9. The Commission issued remedial orders with a service, repair, and replacement exemption, although the remedial orders remain suspended pending final resolution of the complainant's appeal of the USPTO's final written decisions finding the asserted claims invalid. *See id.* at 86–87.

asserted had a full and fair opportunity to litigate its position. *Id.* at 56 (citing *Certain Three-Dimensional Cinema Sys*. & *Components Thereof*, Inv. No. 337-TA-939, EDIS Doc. ID 588763, Comm'n Op. at 53 (Aug. 23, 2016)). According to Complainants, all of those elements are satisfied here, and the Commission therefore should likewise conclude that no public interest concerns warrant denying their requested remedy. *See id.* at 56–57.

In reply, Apple asserts that collateral estoppel does not apply here. *See* RBr. (Reply) at 35–36. Apple reasons that the public interest issues now at issue are different from the ones in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, where Commission briefing was completed months earlier and related to a different feature. *Id.* at 35. Apple further alleges that, in assessing the "propriety of remedial orders, the Commission should consider public interest issues on an ongoing basis, based on the present facts." *Id.* Apple points out that the Commission has never applied collateral estoppel regarding the public interest, and Apple further asserts that the Commission has rejected the application of estoppel to the public interest in the past. *Id.* (citing, *inter alia*, *Certain Mobile Elec. Devices & Radio Frequency & Processing Components Thereof (II)*, Inv. No. 337-TA-1093, Final ID, 2019 WL 2058009, at *23 (Mar. 26, 2019)). Apple further argues that the particular public interest questions "posed in the Commission's Notice of Review indicate that issues specific to this Investigation will bear on the Commission's findings," and the Commission should therefore consider that briefing. *Id.* at 36.

b. Analysis

The Commission concludes that collateral estoppel does not bar Apple from arguing the merits of the public interest. The statutory language of section 337 requires the Commission to consider the public interest in each investigation before issuing a remedy. *See, e.g.*, 19 U.S.C. § 1337(d)(1) ("If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned . . . be excluded

from entry . . . *unless, after considering* the effect of such exclusion upon the [public interest factors], it finds that such articles should not be excluded from entry." (Emphasis added)). Relying on the Commission's decision in previous investigations alone does not satisfy the statutory mandate to consider the public interest. *See Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op at 28 ("[T]he statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found."), 28 n.25 ("The Commission has a statutory duty to consider the public interest."). While the Commission's reasoning in *Wearable Electronic Devices* is in some instances applicable here (as discussed below), the Commission will consider Apple's arguments anew. Furthermore, unlike the arguments in *Wearable Electronic Devices*, the public interest arguments here involve both the Apple Watches' blood oxygen feature and electrocardiogram ("ECG") recording feature. Moreover, any estoppel would be inapplicable to non-party comments.

4. The Public Interest Factors

a. Public Health and Welfare

In general, Apple argues that Complainants' requested remedy will adversely affect the public health and welfare because it will "prevent consumers and medical researchers from future access not only to the Blood Oxygen feature[50] that Complainants have accused of infringement, but also to a host of other health, wellness, and safety features—including ones known to be lifesaving." RBr. at 83. Apple primarily points to the ECG recording feature that was at issue in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. Apple further explains that, "[i]n addition to numerous consumer connectivity functions—including cellular capability,

[50] The "Blood Oxygen feature" refers to the infringing pulse oximetry feature.

messaging, email, access to the Internet, and navigation," the Apple Watches subject to exclusion "also offer the IRN[51] feature and the ECG app, which provide notification of a potentially fatal cardiac condition (atrial fibrillation)[52] and allow users to monitor their heart rhythm and share the data with their doctors." *Id.* Apple further argues that Complainants' proposed exclusion order would also be a "major setback for medical research, where Apple Watch plays a critical role." *Id.* at 84.

Apple additionally argues that any remedial order should include a service, repair, and replacement exemption for consumers who have permissibly obtained an Apple Watch with the accused blood oxygen feature. *E.g.*, *id.* at 74. Apple also argues that the enforcement of any remedial order should be delayed for twelve months to "allow other device manufacturers to scale up their production capacity and address supply chain constraints that will limit supply of alternatives" and to "allow Apple sufficient time to prepare and implement its proposed design-around, and to allow the design-around to go through the necessary approval process." *E.g.*, *id.* at 89.

As discussed below, the Commission has determined that any adverse effect on the public health and welfare from the Commission's remedial orders can be mitigated by the provided service, repair, and replacement exemption. There are numerous reasonable substitutes for infringing Apple Watches available in the United States for both Apple Watch users who use the devices for personal, health-related use and for users who are using infringing Apple Watches to participate in medical studies. Additionally, the Commission's remedial orders, in view of the

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[51] "IRN" stands for "irregular rhythm notification." The Apple Watch SE, which is not subject to the Commission's remedial order includes the IRN feature. *See* RBr. at 84 n.51.

[52] "Atrial fibrillation" is sometimes abbreviated herein as "AFib."

service, repair, and replacement exemption, will have no meaningful effect on medical research. Last, Apple has not shown the need for any delay in the enforcement of the Commission's remedy.

i. Reasonable Substitutes

a) The Parties' Arguments

Apple's Arguments

Regarding the scope of reasonable substitutes, Apple asserts that the Accused Products "include numerous features pertinent to public health and public welfare, and relevant to the reasonable substitute inquiry," such as: (1) they are smartwatches (*i.e.* they have "features similar to a smartphone," including telecommunications and location-sharing capabilities and accessibility features that may assist the hearing or visually-impaired); (2) they are "fitness tracking devices"; and (3) they are "health and wellness devices" that include, for example, ECG, IRN, and HHRN[53] features, and have also been authorized by the FDA. RBr. at 64–66. Apple declares that, "[b]ecause the Accused Apple Watches are multi-featured devices intended to serve a wide spectrum of potential users, consumers purchase the Accused Apple Watches to obtain different combinations of the above-described features." *Id.* at 66; *see also id.* at 66–67. And, according to Apple, while "[o]ther smartwatches . . . share some functionality with Apple Watches," they "may lack crash-detection or AFib History, and many of them lack ECG, temperature tracking, and/or fall detection features." *Id.* at 70. Apple further argues that Complainants erroneously "attempt to narrow the range of features relevant to the public interest inquiry to only 'health, safety, and wellness features.'" RBr. (Reply) at 40 (citing

[53] "HHRN" stands for "high heart rate notification." The non-infringing Apple Watch SE includes this feature. *See* CBr. (Reply) at Ex. 93 (McGavock Declaration) at ¶ 39 (Table 1).

Thermoplastic-Encapsulated Motors, Inv. No. 337-TA-1073, RD, 2018 WL 10758211, at *5 (Nov. 27, 2018); *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm'n Op., 2013 WL 10734395 at *80 (Nov. 27, 2018)). Apple explains that "[t]he protected interest is the public's ability to access the numerous relevant features in the Accused Apple Watches, just as the public was interested in accessing the relevant active safety system functionality in *Certain Table Saws*." *Id.* at 42.

Apple specifically argues that Masimo's W1 Watch should not be considered a reasonable substitute because (1) it is not available to U.S. consumers in "any material quantity," (2) it is not a "smartwatch," (3) it allegedly has not been shown to "reliably measure physiological parameters," and (4) it is allegedly not manufactured in sufficient quantity to meet the demand created by an exclusion order. RBr. at 63.

Complainants' Arguments

Complainants argue that "reasonable substitutes" should be defined the same way as in *Wearable Electronic Devices*, *i.e.*, as watches with a "range of health, safety, and wellness features." CBr. at 81 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 75). Complainants explain that, under *Table Saws*, a "reasonable substitute" is defined by the "protected interest" in the features benefitting the public health and welfare. *Id.* (citing *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 3). Complainants then declare that the public health and welfare is not impacted by consumers' inability to have smartwatches generally, and thus, "reasonable substitutes" should be defined as they were in *Wearable Electronic Devices*. *See* CBr. (Reply) at 37.

Regarding specific substitutes, Complainants rely in part on following chart from the Commission's Opinion in *Wearable Electronic Devices*, Inv. No. 337-TA-1266:

TABLE 1: SELECTED SMARTWATCH FEATURES PROMOTED BY DEVICE MANUFACTURERS

	Apple		Competitors				
	Apple Watch (Series 8) [A]	Apple Watch (SE 2nd Gen) [B]	Samsung Galaxy (Watch 5) [C]	Fitbit (Sense2) [D]	Fossil (Gen 6) [E]	Garmin (Venu 2 Plus) [F]	Zepp (Amazfit GTS4) [G]
GPS	✓	✓	✓	✓	✓	✓	✓
Emergency SOS Capability	✓	✓	✓	×	×	✓	×
Water Resistant	✓	✓	✓	✓	✓	✓	✓
Speaker and Microphone	✓	✓	✓	✓	✓	✓	✓
24+ Hour Battery Life	✓	✓	✓	✓	✓	✓	✓
iOS Compatability	✓	✓	×	✓	✓	✓	✓
Cellular Connectivity	✓	✓	✓	✓	✓	✓	✓
Personalizable Design	✓	✓	✓	✓	✓	✓	✓
Health Functions							
ECG	✓	×	✓	✓	×	×	×
HHRN	✓	✓	✓	✓	-	✓	✓
IRN	✓	✓	-	✓	-	✓	✓
Low Cardio Fitness Notifications	✓	✓	-	✓	✓	✓	✓
Blood Oxygen	✓	×	✓	✓	✓	✓	✓
Fall Detection	✓	✓	✓	×	×	✓	✓
Crash Detection	✓	✓	✓	×	×	✓	✓
Wrist Temperature	✓	×	✓	✓	×	×	×
Sleep Monitoring	✓	✓	✓	✓	✓	✓	✓

CBr. at 83; *Wearable Elec. Devices*, Inv. No 337-TA-1266, Comm'n Op. at 77. Complainants point out that most of these watches offer the blood oxygen feature and at least the Samsung Galaxy (Watch 5) and Fitbit (Sense 2) include an ECG recording feature. Complainants allege that "[a]ll of the wearables manufactured by third parties identified in the above chart would be reasonable substitutes for the infringing Apple Watches." *Id.* Aside from reliance on *Wearable Electronic Devices*, Complainants argue:

> Garmin's vivoactive®, Fenix®, epix™, Venu®, and Forerunner® series all have watches that include a blood oxygen feature. Google's Pixel watch[ ] includes a blood oxygen feature. Samsung's Galaxy 5 watch contains a blood oxygen feature. The Fitbit Versa 4™, Sense 2™, and Charge 5™ also contain blood oxygen features. The Fossil Gen6 contains a blood oxygen feature as well. These smartwatches contain many of the features found in the Apple Watch and many sell at lower prices. Masimo's W1, available directly to consumers, offers continuous clinical-grade pulse oximetry as well as other health features. It is currently used in hospitals as well, outside the United States. . . . Masimo's Freedom smartwatch will also include pulse oximetry and other health features and is expected to launch in the Fall of this year. Moreover, Masimo offers its

> blood oxygen sensor as a module to third parties who can integrate the module in their own smartwatches.
>
> Numerous other competitive products are reasonable substitutes for the ECG functionality of the infringing products. This includes the Garmin Venu 2 Plus, Google Pixel, Samsung Galaxy 5, Fitbit Sense 2, and Fitbit Charge 5. As the Commission held in [*Wearable Electronic Devices*], the public's interest in these health features of the Apple Watch is insufficient to overcome the statutory remedy given the availability of competing substitutes.

Id. at 64–65 (citations and footnotes omitted).

Complainants also specifically argue that Masimo's W1 Watch is a reasonable substitute for the infringing Apple Watches because it offers many of the same health features that the public would be interested in having access to, including blood oxygen measurements. *See* CBr. at 83–84. Complainants point out that the Final ID found that the W1 Watch can reliably measure physiological parameters, such as blood oxygen levels. *Id.* (citing, *inter alia*, Final ID at 60–63); *see also id.* at 38–39. Complainants further argue that the W1 Watch should not be outside the scope of reasonable alternatives for not being produced in a sufficient quantity alone to meet all consumer demand created by any exclusion order because the Commission does not require any alleged substitute to satisfy that demand alone. *See* CBr. (Reply) at 37.

Complainants further argue that there is no evidence that other manufacturers of suitable alternatives do not have capacity to meet consumer demands." CBr. (Reply) at 39; *see also id.* at 39–41. Complainants point out that Apple itself could manufacture its Apple Watch SE, "which contains virtually all the same features as the infringing products, or return to producing the Apple Watch Series 4 or 5, which also included ECG," but not blood oxygen measurements. *Id.* (citing CBr. Ex. 93 at ¶¶ 22–24).

b) Non-Party Comments

Some researchers stated that other devices can replace Apple Watches:

> Given our combined expertise in the theory, design, financing, execution, and dissemination of medical research, we see no reason why it is not possible to replace the Apple Watch in pending health applications with alternative wearable devices from *Fitbit, Withings, Garmin* and others that are able to provide human motion, heart function and oxygen saturation information. Several of these companies also readily provide the Application Programming Interface (API) code that allows connectivity and data transfer to the investigator's systems.

Valero-Cuevas Comments, EDIS Doc. ID 798257, at 2; *see also id.* at 2–3. Other researchers, medical professionals, and commenters submitted filings indicating a preference for Masimo's technology, with some going so far as discouraging reliance on Apple's blood oxygen saturation feature. *See, e.g.*, McCarthy Stmt., EDIS Doc. ID 789080; Waddell Stmt., EDIS Doc. ID 789029; Albert Stmt., EDIS Doc. ID 790883; Ward Stmt., EDIS Doc. ID 790884; Yazdani Stmt., EDIS Doc. ID 791177; Goldstein Stmt., EDIS Doc. ID 791179; MDMA Stmt., EDIS Doc. ID 791167; PSMF Stmt., EDIS Doc. ID 791175; Pronovost Stmt., EDIS Doc. ID 791162.

Still other researchers indicated a preference for the Apple Watch. *See, e.g.*, NJH Stmt., EDIS Doc. ID 790602, at 1; Passman Comments, EDIS Doc. ID 797813, at 1–2; Freimer Comments, EDIS Doc. ID 797817, at 1–2; Calkins Comments, EDIS Doc. ID at 797827, at 1–2; MacRae Comments, EDIS Doc. ID 797826, at 1–2; Saxon Comments, EDIS Doc. ID 797811, at 1–2; AHA Stmt., EDIS Doc. ID 791476, at 3.

c) Analysis

The Commission assesses the scope of reasonable alternatives from the perspective of public interest concerns raised in an investigation. *See Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 73–74 (assessing the scope of reasonable substitutes from the perspective of each of the three public interest concerns raised by Apple); *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 9 ("The protected [public health and welfare] interest here is the public's ability to purchase table saws with [active injury management technology ('AIMT')]

functionality, not the ability to purchase AIMT table saws with a specific feature set that is unrelated to the efficacy of the AIMT functionality."). The Commission notes that Apple argues, regarding the public health and welfare, that the Apple Watches' ECG feature should also be considered because all accused Apple Watches that have the blood oxygen feature also have the ECG feature, and thus an exclusion order affecting blood oxygen feature-containing Apple Watches would also result in the exclusion of ECG feature-containing Apple Watches. RBr. at 60. Therefore, for the purposes of the public health and welfare factor, because the ECG feature is a health related feature, the Commission considers the scope of "reasonable substitutes" to include substitutes that offer a wide range of health, safety, and wellness features, including those that allow consumers to measure blood oxygen levels and that can record ECGs, although a single device need not have the capability to measure both oxygen levels and record ECGs. *See Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 75. While it is not ideal for an individual or research participant to wear two wearable electronic devices to obtain all of the desired features, the inconvenience of doing so is not significant enough to rise to the level of a public interest concern, especially in view of the countervailing interest of protecting intellectual property rights. *See, e.g.*, *Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof*, Inv. No. 337-TA-422, Comm'n Op. at 9 (July 21, 2000); *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 45–46.

Apple stretches the public health and welfare public interest factor too far by seeking to require reasonable substitutes for this factor to also have telecommunications features, location tracking features, "smart" wallet and keys features, and accessibility features. The connection to the public health and welfare with those features is too attenuated to rise to the level of a public interest concern, especially when some of those alleged Apple Watch features require a paired

iPhone (which can independently perform many of those functions). *See* CBr. (Reply) at 37. And again, "[t]he correct assessment . . . for 'reasonable substitutes for the devices subject to the exclusion order,' [is] not whether 'every consumer cannot obtain the exact device desired.'" *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op., at 85 (quoting *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm. Op. at 120, and citing *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 9).[54]

In view of the above, the scope of reasonable substitutes for the public health and wellness factor in this investigation include: Masimo's W1 and Freedom Watches (blood oxygen feature), Google's Pixel watch (blood oxygen and ECG features),[55] Samsung Galaxy Watch 5 (blood oxygen and ECG features),[56] Fitbit (Versa 4™ (blood oxygen feature), Sense 2™ (blood oxygen and ECG features), and Charge 5™ (blood oxygen and ECG features)),[57]

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[54] While "reasonable substitutes" also considers "price points," *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 8, Apple appears to allege that price point is an issue regarding only Masimo's soon-to-be-released Freedom Watch. While the Freedom Watch will be priced higher than the base infringing Apple Watch models (*see* RBr. at Ex. 3 at ¶ 25 ($999 for the Freedom Watch compared to the Apple Watch Series 8, which starts at $399)), infringing Apple Watch models can be comparable in price ($799) based on consumer choices (*see* RBr. at 77 (citing, *inter alia*, RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011). Other reasonable substitutes are even more comparable in price. For example, the Garmin Venu® 2 Plus is available for $449, s*ee* CBr. at Ex. 49 (https://www.garmin.com/en-US/p/730659), and the Garmin vivoactive® is available for $349, *see* CBr. at Ex. 7 (https://www.garmin.com/en-US/p/643399).

[55] CBr. at Ex. 12 (https://store.google.com/product/google_pixel_watch_specs?hl=en-US); CBr. at Ex. 50 (https://support.google.com/googlepixelwatch/answer/12759285?hl=en).

[56] CBr. at Ex. 13 (https://www.gadgetstowear.com/measure-blood-oxygen-on-galaxy-watch-5/); CBr. at Ex. 51 (https://www.androidcentral.com/wearables/measure-ecg-samsung-galaxy-watch-5).

[57] CBr. at Ex. 14 (https://www.fitbit.com/global/us/products/smartwatches/versa4?sku=523BKBK); CBr. at Ex. 52 (https://help.fitbit.com/articles/en_US/Help_article/2457.htm).

Fossil (Gen 6) (blood oxygen feature),[58] Garmin (vivoactive® (blood oxygen feature),[59] Fenix® (blood oxygen feature),[60] epix™ (blood oxygen feature),[61] Venu® (blood oxygen feature),[62] Venu® 2 Plus (ECG feature),[63] and Forerunner®[64] series (blood oxygen feature)), and Zepp (Amazefit GTS4). *See* CBr. at 64–66; CBr. (Reply) at 37 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 37). These watches (alone or combined with each) include one or both of the blood oxygen features and the ECG features (as well as the IRN, HHRN, or other features), and thus are reasonable substitutes.[65]

The Commission agrees with Complainants that the W1 Watch can serve as a reasonable substitute for the infringing Apple Watches as to the public health and welfare factor. *See, e.g.*, CBr. (Reply) at 38–39. In protesting against the suitability of this product, Apple asserts that the W1 Watch "has not been shown to reliably measure physiological parameters." RBr. at 68.

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[58] CBr. at Ex. 15 (https://www.fossil.com/en-us/watches/learn-more/gen-6-wellness/).

[59] CBr. at Ex. 7 (https://www.garmin.com/en-US/p/643399).

[60] CBr. at Ex. 8 (https://www.garmin.com/en-US/p/735542).

[61] CBr. at Ex. 9 (https://www.garmin.com/en-US/p/760778).

[62] CBr. at Ex. 10 (https://www.garmin.com/en-US/p/801643).

[63] CBr. at Ex. 49 (https://www.garmin.com/en-US/p/730659).

[64] CBr. at Ex. 11 (https://www.garmin.com/en-US/p/886785).

[65] We note that Complainants argue, in response to Apple's arguments regarding the ECG feature, that the Apple Watch SE should be considered a reasonable substitute for purposes of the public health and welfare factor because it was considered a substitute in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. *E.g.*, CBr. at 66. However, in that investigation, the record included specific, reliable evidence that the Apple Watch SE, when combined with accessories, could be used to record ECGs and therefore was a reasonable substitute. *E.g.*, *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 75–76 (including n.39). Complainants point to no such evidence in the record in this investigation. Accordingly, the Commission rejects this argument.

However, the Final ID properly found that "the variation in the measurements [of oxygen saturation by the W1 Watch] appears to be consistent with FDA guidance regarding pulse oximetry." Final ID at 62 n.18. And, regarding Masimo's Freedom Watch, Masimo's Chief Operating Officer, Bilal Muhsin, stated in a declaration:

> In Fall 2023, Masimo intends to launch the Masimo Freedom smartwatch. The Masimo Freedom grew out of the Masimo W1, and will also provide clinical-grade pulse oximetry, as well as unparalleled real-time health indicators such as pulse rate, and unique scores and indexes such as Hydration Index, and Stress Index. The Masimo Freedom will be capable of measuring all the same variables as the Masimo W1, but will also include other traditional smartwatch capabilities, and safety features such as fall detection.

CBr. at Ex. 53 at ¶ 5. Apple acknowledges that the Freedom Watch is a planned replacement for the W1 Watch. *See* RBr. at 87, 88 n.54 (noting a March 28, 2023 Masimo press release regarding pre-sale launch of the Freedom Watch). Thus, the Freedom Watch is also a reasonable substitute.

ii. The Remedial Orders Will Have at Most a Minimal Adverse Effect on Medical Research

In brief, the Commission finds that its remedial orders will have, at most, a minimal adverse effect on medical research.

a) The Parties' Arguments

Apple's Arguments

Apple argues that Complainants' requested remedial orders will adversely affect medical studies using the infringing blood oxygen feature, as well as studies using the ECG recording feature, of the accused Apple Watches. *See* RBr. at 57–62. Apple reasons that studies using the Apple Watches' ECG feature should also be considered in assessing impact on the public health and welfare because all accused Apple Watches that have the blood oxygen feature also have the ECG feature, and thus an exclusion order affecting blood oxygen feature-containing Apple

Watches would also result in the exclusion of ECG feature-containing Apple Watches. *See id*. at 60. Apple further alleges that a "key benefit of [the] Apple Watch for . . . studies is that researchers can use the multiple health and wellness metrics available through the Accused Apple Watches (as opposed to a single data field), helping to advance scientific discovery by identifying how various metrics relate to certain conditions." *Id.* at 58. Apple points to several specific studies. *See id.* at 57–61. Apple further points to certain research areas for which it believes the accused Apple Watches "could potentially be impactful," including those related to racial disparities in pulse oximetry measurement accuracy. *Id.* at 59–60. Apple further argues that "the broad availability of [the] Apple Watch to consumers enables researchers more generally to conduct decentralized research, which helps promote higher enrollment and more diverse patient populations." *Id.* at 61. Apple thus concludes that the Commission should find that Complainants' requested remedial orders would undermine important medical studies, and because it would allegedly not be practical to tailor any remedial orders to permit the importation or sale of Apple Watch models for use in clinical trials and other medical research, the Commission should deny Complainants a remedy altogether. *See id.* at 62.

Complainants' Arguments

Complainants acknowledge that ClinicalTrials.gov, a governmental database of clinical trials maintained by the U.S. National Library of Medicine, lists 109 studies that use or have used the Apple Watch, including 67 that remain ongoing. CBr. at 77 (citing CBr. at Ex. 24 and Ex. 25). However, Complainants state that most of these ongoing studies focus on heart rate features that are also available on the Apple Watch SE, which the parties agree would not be subject to exclusion. *Id.* Complainants declare that, while nine studies use the blood oxygen feature of the infringing Apple Watches, none of those studies will be affected by any exclusion

order because they have already ended, are conducted outside of the United States, and/or do not require pulse oximetry measurements specifically from the infringing Apple Watches (as opposed to reasonable substitutes). *See id.* at 78–79; *see also* CBr. (Reply) at 30–35. As for studies using the ECG feature, Complainants argue that the Commission already rejected those arguments made by Apple in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. *See* CBr. (Reply) at 30. Last, Complainants address Apple's argument that the "broad availability of Apple Watch to consumers enables researchers more generally to conduct decentralized research." *Id.* at 36 (quoting RBr. at 61). In response, Complainants assert that there are reasonable substitutes available, "including the Apple Watch SE and third-party devices from Samsung, Google, Fitbit, and others." *Id.* (citing CBr. at 64–67, 82–84; CBr. at Ex. 93 at Table 1, ¶¶ 28–39).

b) Non-Party Comments

Some non-party researchers have stated that the Apple Watch is important to their studies. *See, e.g.*, NJH Stmt., EDIS Doc. ID 790602, at 1 ("[M]y research group has found the Apple Watch to be an exceptional device that accurately measures important parameters such as heart rate, physical activity, and oxygen saturation."); Stanford Stmt., EDIS Doc. ID 791060, at 1 ("The oxygen saturation feature of the Apple Watch is a highly accurate device feature, with performance characteristics fully comparable to medical device standards for oximeters."); Passman Comments, EDIS Doc. ID 797813, at 1–2 ("[I]f Apple Watch is excluded for an extended period of time, our REACT-AF study and other critical research that uses this technology will be altogether shut down."); Freimer Comments, EDIS Doc. ID 797817, at 1–2; Calkins Comments, EDIS Doc. ID at 797827, at 1–2; MacRae Comments, EDIS Doc. ID 797826, at 1–2; Saxon Comments, EDIS Doc. ID 797811, at 1–2; AHA Stmt., EDIS Doc. ID 791476, at 3–4.

On the other hand, some researchers have stated that other devices can replace infringing Apple Watches:

> Given our combined expertise in the theory, design, financing, execution, and dissemination of medical research, we see no reason why it is not possible to replace the Apple Watch in pending health applications with alternative wearable devices from *Fitbit, Withings, Garmin* and others that are able to provide human motion, heart function and oxygen saturation information. Several of these companies also readily provide the Application Programming Interface (API) code that allows connectivity and data transfer to the investigator's systems.

Valero-Cuevas Comments, EDIS Doc. ID 798257, at 2; *see also id.* at 2–3. Other researchers and commenters have expressed a preference for Masimo's technology and even discouraged the reliance on Apple's blood oxygen feature. *See* Ward Stmt., EDIS Doc. ID 790884, at 2 ("I am . . . very concerned about the proliferation of 'medical devices' like the Apple Watch with pulse oximetry. These are not 'medical devices' as the FDA would use the term. Indeed, I understand only software associated with the ECG feature of certain Apple Watches is FDA cleared. . . . Despite this, it is my belief that confusion abounds in that many patients and medical professionals believe or at least use devices such as the Apple Watch as if they are FDA approved."); *see also* Goldstein Stmt., EDIS Doc. ID 791179.

c) Analysis

The Commission finds that the remedial orders will have only a minimal effect on formally planned or ongoing medical studies that will not rise to the level that warrants denying a remedy.[66]

[66] Recall that Apple asserts that it "would not be practical to tailor any remedial orders to permit importation or sale of Apple Watch models for use in clinical trials and other medical research." RBr. at 62.

First, even without the service, repair and replacement exemption, any limited exclusion order would cover only new imports of infringing Apple Watches after the expiration of the period of Presidential review (estimated to be late 2023) until the earlier of Apple's clearance of a redesign or the expiration of the patents subject to the section 337 violation (August 2028). *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op at 70–71. Thus, the Commission's remedy will not prevent current study participants using infringing Apple Watches from continuing to participate in research studies. *See id*. Further, with this exemption, current research study participants who are using infringing Apple Watches who encounter a need for service, repair, or replacement of their device to continue participation in that study will be able to obtain such service, repair, or replacement. *See id.* Moreover, as Complainants point out, there is little evidence of ongoing studies that require infringing Apple Watches, as opposed to any of the many reasonable alternative devices (discussed above). *See* CBr. at 77–79; CBr. (Reply) at 31–35. Thus, ongoing research studies that are not enrolling new participants will not be affected by the Commission's remedial orders.

Second, the Commission's remedial orders will have at most a minimal adverse effect on ongoing studies that remain open to new participants. As just noted, the Commission's remedy will not prevent current study participants using infringing Apple Watches from continuing to participate in research studies using those infringing devices. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 70–71. Also as just noted, current owners of infringing Apple Watches will not lose their devices as a result of the Commission's remedial orders, and the Commission's remedial orders will also allow those owners to have their products serviced, repaired, or replaced. Moreover, potential new participants who already own or may own infringing Apple Watches as of the date the Commission's remedial orders become final within

the meaning of 19 U.S.C. § 1337(j)(4) will still be able to participate in those studies. *See id.* And the record reflects that there are at least [redacted] such potential participants. *See* RBr. at Ex. 6 (Dippon[67] Decl. [redacted]. Furthermore, the [redacted] figure undercounts the number of potential participants because it does not capture approximately a year's-worth of imports of infringing Apple Watches. Thus, to the extent any study depends on having a large number of participants with infringing Apple Watches, a large number of potential participants is already present in the United States. Additionally, the record includes no specific evidence providing a reasoned basis why the already large number of infringing Apple Watches in the United States is insufficient for any such study. In any event, as Complainants point out, there is little evidence of ongoing studies that are accepting new participants who are located inside of the United States. *See* CBr. at 77–79; CBr. (Reply) at 31–35. In sum, the Commission's remedial orders will have at most a minimal adverse effect on ongoing studies that remain open to new participants.

Third, the Commission's remedial orders will also have, at most, a minimal adverse effect on formally planned but not yet started studies that are enrolling participants. As noted above, there are likely well over [redacted] potential participants in the United States, and the Commission's orders will also allow those owners to have their products serviced, repaired, or replaced. Thus, to the extent any studies depend on having a large number of participants with infringing Apple Watches, infringing Apple Watches have already been broadly sold in the United States such that there are already a large number of potential study participants. Neither

[67] Christian M. Dippon, PhD, is an Apple expert witness on the public interest. *See* RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 1.

Apple nor the non-party commenters have shown that the already large number of infringing Apple Watches in the United States is insufficient for any study. Additionally, as Complainants point out, there is little evidence of formally planned but not yet started studies that are enrolling participants and that require the infringing Apple Watches, as opposed to non-infringing Apple Watches or reasonable alternative devices. *See* CBr. at 77–79; CBr. (Reply) at 31–35. And again, the Commission's remedial orders will have no effect on ongoing research studies that are accepting new participants when those participants use an Apple Watch that they owned prior to the date the Commission's remedial orders becomes final within the meaning of 19 U.S.C. § 1337(j)(4), as discussed in more detail in the following subsection. In sum, the Commission's remedial orders will also have, at most, a minimal adverse effect on formally planned, but not yet started, studies that are enrolling participants.

As for studies that have not yet been formally planned, the Commission finds that any alleged harm related to the public health and welfare is too speculative to rise a public interest concern.

iii. The Service, Repair, and Replacement Exemption

The Commission has determined that its remedial orders shall include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) and issuance of the orders when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations; and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period for Presidential review when those imports are to service and/or repair

Apple Watches outside of warranty obligations.[68] While the parties' arguments regarding the service, repair, and replacement exemption primarily relate to the United States consumers public interest factor, it is also relevant to the public health and welfare factor as the exemption allows research participants using infringing Apple Watches pursuant to a research study to have that device at least serviced and repaired, and replaced if it is under warranty, such that they may be able to continue the study using the same device they started with. That said, the parties' arguments and our analysis in this section primarily relate to the United States consumers public interest factor, which is discussed more fully below in section V.B.4.d.

a) The Parties' Arguments

Apple's Arguments

Apple argues that "[a]ny remedial order should protect consumers who have permissibly obtained an Apple Watch with the accused Blood Oxygen feature by permitting Apple to provide technical support, service, repair, and replacement services, both with respect to units under warranty or other applicable service and repair obligations, and to units no longer under warranty." RBr. at 74 (citing, *inter alia*, *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 88–92). Apple asserts that the "accused Apple Watches are subject to a manufacturer's warranty that requires Apple to repair or replace products for one or two years, depending on the model." *Id.* at 74–75 (citing RBr. at Ex. 4 (Watkins[69] Decl.) at ¶¶ 7–15; RX-0930 at .0003; RX-

[68] As explained *infra* at note 72, Commissioner Kearns does not join the ajority's determination to set the cutoff date for the exemption to the expiration of the period of Presidential review.

[69] Mr. Scott Watkins is an Apple employee. *See* RBr. at Ex. 4 (Watkins Decl.). He is "legal counsel for AppleCare at Apple Inc." *Id.* at ¶ 2.

0926 at .0002; RX-0929 at .003; RX-0926 at .0003; RX-0927; Tr. (Land[70]) at 968:11–18). Apple explains that, under Apple's warranties, "consumers expect that if Apple replaces their Watch having the Blood Oxygen feature with 'the same model,' the replacement Watch will also include the Blood Oxygen feature." *Id.* at 75 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶ 11). Apple further argues that "[m]any consumers also purchase extended service and support coverage for their Watch devices through Apple's AppleCare+ program." *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 16–24; RX-0926 at .0004)). Apple further declares that it "provides out-of-warranty repair and replacement for Watch devices that are beyond the warranty period," for up to five years. *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 25–27, 30–33; RX-0927 at .0002–0003; RX-0928C; Tr. (Land) at 968:19–969:1. While Apple's warranties provide a refund option in place of repairing or replacing, Apple asserts that some U.S. states require product manufacturers to make available service parts for repair for five to seven years, regardless of warranty status, and a refund is also not a suitable option for consumers who purchased AppleCare+. *Id.* Apple further points out that "some consumers purchase warranties or insurance contracts through third party vendors, such as mobile device carriers and resellers, [redacted] *Id.* at 77 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 28–29).

Next, Apple argues that the repair and replacement exemption should cover both repair and replacement to protect consumers. *See* RBr. at 79–80. Apple asserts that the "[manufacturer's suggested retail price] of Apple Watch devices with the accused Blood Oxygen

[70] Brian Land leads a health sensing hardware group at Apple. *See, e.g.*, Final ID at 6.

feature is not insignificant," ranging from $399 to $799, which includes a price range consistent with previous Commission repair and replacement exemptions. *Id.* at 77 (citing, *inter alia*, RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011; *Certain Robotic Floor Cleaning Devices & Components Thereof*, Inv. No. 337-TA-1252, Comm'n Op. at 77–78 (Apr. 13, 2023)). Apple adds that "[r]equiring Apple to refund the purchase price rather than repair or replace a consumer's Watch could adversely impact consumers who may need a replacement Watch to allow them to continue ongoing monitoring and collection of health, wellness, and fitness data." *Id.* at 78. Apple then declares that [redacted] *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 31–33). According to Apple, "[e]xcluding replacement units from an exemption would be contrary to millions of consumers' expectations." *Id.* at 79 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 6, 15, 24, 27–29, 34; RX-0926; RX-0927; RX-0929; RX-0930).

Apple next argues that the cutoff date for a repair and replacement exemption should be the date that any remedial orders become final within the meaning of 19 U.S.C. § 1337(j)(4), in other words, the end of the period of Presidential review. RBr. at 80 (citing, *inter alia*, *Fitness Devices*, Inv. No. 337-TA-1265, Notice of Comm'n Determination to Reconsider the Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders, 88 Fed. Reg. 30158, at 30158–59 (May 10, 2023)). According to Apple, "[t]his cutoff date protects consumers who—through no fault of their own—purchase an Accused Apple Watch between the date of any remedial order and when it becomes final." *Id.*; *see also id.* at 80–81. Apple asserts that "[a]ny remedy should also include an exemption permitting continued sale of new AppleCare+ service

and repair plans during and after the Presidential Review Period for any permissibly obtained Apple Watch devices." *Id.* at 81.

Apple further argues that the exemption should apply to any products imported prior to the end of the period of Presidential review, regardless of whether they were purchased by users prior to that cutoff date. RBr. at 81–82. According to Apple, Apple Watches are sold by Apple directly to consumers and also through other retail channels such as retailers who may continue to receive shipments of imported Apple Watch devices up through the Presidential Review Period, subject to the posting of any required bond. *Id.* at 81. Apple declares that "[t]hese retailers, which were not named as respondents and will not be subject to any CDO, may then continue to sell the subject Watch devices," and consumers "purchasing these Watch devices should also be protected by an exemption for repair or replacement" because "[t]hey will have the same legitimate expectation regarding the availability of repairs or replacements as consumers who purchased an article before the cutoff date." *Id.* at 81–82.

Complainants' Arguments

Complainants argue that "Apple presented no evidence of consumer harm that would justify an exemption for repair or replacement of infringing articles or parts." CBr. at 85–86 (citing *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 88–92); *see also* CBr. (Reply) at 43 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 50). Complainants add that the Commission should not allow an exemption for repair or replacement of products under warranty because "Apple's warranties provide an option for a refund, rather than a replacement." CBr. (Reply) at 86 (quoting RX-0925 at .003 at (iii); RX-0929 at .003; RX-0930). Complainants further declare that "[t]here is no evidence in the record that consumers expect

repair or replacement for products under warranty, and Apple's refund provision gives consumers an alternative option." *Id.*

Complainants further argue that, if the Commission were to provide a service, repair, and replacement exemption, the "cutoff date for any repair and replacement should follow Commission precedent and apply to products sold to an end user before the date of the remedial orders." CBr. at 86 (citing *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 88–90). Complainants additionally assert that any "exemption should not apply broadly to all imported products and should be limited to products sold to an end user, because there is no consumer need for repair or replacement of products that have been imported, but not yet sold." *Id.* In arguing that the exemption should not extend through the period of presidential review, Complainants point out that "Apple can inform customers by providing notice of the remedial order." CBr. (Reply) at 43.

b) Analysis

The Commission has concluded that its remedial orders shall include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations (regardless of whether the warranty was purchased through Apple or a third party vendor); and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period for Presidential review when those imports are to service and/or repair Apple Watches outside of any warranty obligations. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81; *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89–92.

Here, also like in *Wearable Electronic Devices*, the service, repair, and replacement exemption is also justified as to the United States consumers public interest factor based on consumers' reasonable expectations. *See id.* at 80–81; *see also Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89–92. Apple Watches are subject to a manufacturer's warranty that requires Apple to repair or replace products for one or two years, depending on the model. RBr. at Ex. 4 (Watkins[71] Decl.) at ¶¶ 7–15; RX-0930 at .0003; RX-0926 at .0002; RX-0929 at .003; RX-0926 at .0003; RX-0927; Tr. (Land) at 968:11–18; *see also Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81. Many consumers have also purchased extended service and support coverage (*i.e.*, warranty coverage) for their Apple Watch devices through Apple's AppleCare+ program. RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 16–24; RX-0926 at .0004). And some consumers have purchased warranties or insurance contracts through third party vendors, such as mobile device carriers and resellers, which Apple ultimately supports by [redacted]

[redacted]

RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 28–29. Under these warranty programs (such as AppleCare+), consumers expect that, if Apple replaces their device, it will do so with the same model. RBr. at Ex. 4 (Watkins Decl.) at ¶ 11; *see also Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81. Moreover, the cost of infringing Apple Watches is not insignificant, ranging from $399 to $799. RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011. Accordingly, in view of these reasonable consumer expectations, the cost of the infringing Apple Watches, and the Commission's recent decision in *Wearable Electronic Devices*, the Commission has determined to provide a service, repair, and replacement

[71] Mr. Scott Watkins is an Apple employee. *See* RBr. at Ex. 4 (Watkins Decl.). He is "legal counsel for AppleCare at Apple Inc." *Id.* at ¶ 2.

exemption. *E.g.*, *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81; *Robotic Floor Cleaning Devices*, Inv. No. 337-TA-1252, Comm'n Op. at 77–78.

However, the Commission declines to apply the replacement exemption to devices that are outside of warranty. Replacement for products outside of warranty, in view of the fee required by Apple's policies (*see* RBr. at Ex. 4 (Watkins Decl.) at ¶ 25), is tantamount to allowing consumers to purchase a new infringing article, which is outside of the scope of reasonable consumer expectations. *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89–92.

Apple additionally requests that the exemption allow Apple to continue to sell "new AppleCare+ service and repair plans during and after the Presidential Review Period for any permissibly obtained Apple Watch devices." RBr. at 81. The Commission declines Apple's request to permit the sale of AppleCare+ service and repair plans beyond the expiration of the period of Presidential review. If customers have not yet purchased the plans as of the expiration of that period, those customers have no reasonable expectation of those benefits, and Apple can simply stop selling those plans for infringing Apple Watches once the period of Presidential review expires. Moreover, customers will still receive the regular Apple warranty, and having the ability to encourage customers to purchase service and repair plans after this timeframe would give Apple a disproportionate benefit.

For their part, Complainants argue that a refund would suffice instead of a repair or replacement. *E.g.*, CBr. (Reply) at 86. However, the Commission has recently considered and rejected that same argument regarding the same warranties in *Wearable Electronic Devices*. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 81. Here, like in that investigation, Complainants have failed to show that a refund will be adequate to compensate

consumers who are seeking to maintain their Apple Watches or to participate in ongoing health-related studies using the Apple Watch. *See id.*

Next, the parties dispute the appropriate cutoff date for the Commission's service, repair, and replacement exemption. *E.g.*, RBr. at 80; CBr. at 86. In order to mitigate the impact of the remedial orders on United States consumers, the Commission has determined that the exemption shall apply to articles purchased prior to the expiration of the period for Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)). *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Notice (May 5, 2023); 88 Fed. Reg. 30158–60 (Notice of a Commission Determination to Reconsider the Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders) (May 10, 2023).[72]

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[72] Commissioner Kearns does not join the majority in determining to set the cutoff date for the Commission's service, repair, and replacement exemption as the expiration of the period for Presidential review. He would instead use the date the Commission's orders issue. In his view, the Commission's service, repair, and replacement exemption is intended to mitigate the harm to U.S. consumers who—through no fault of their own—would lose access to repair components or replacement devices for articles they purchased at a time when those articles had not been found to have violated section 337. As of the date of the Commission's orders, however, the public is put on notice of a violation that must be remedied, *i.e.* by an exclusion order. He finds that extending the service, repair, and replacement exemption beyond the issuance of the Commission's orders undercuts that remedy to the detriment of the intellectual property holder. Thus, in order to balance the impact of the remedial orders on United States consumers with the public interest in protecting Complainants' intellectual property rights, he would determine that the exemption should only apply to articles purchased prior to the date of the Commission's determination of violation and issuance of the orders. He further notes that this approach is consistent with the Commission's recent approach to this issue. *See, e.g., Certain Variable Speed Wind Turbine Generators & Components Thereof*, Inv. No. 337-TA-1218, Limited Exclusion Order at 2 (Jan. 18, 2022); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067 (Remand), Limited Exclusion Order at ¶ 1 (Nov. 4, 2021); *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. (Revised) at 46 (Jan. 10, 2020); *Certain Magnetic Data Storage Tapes & Cartridges Containing the Same*, Inv. No. 337-TA-1012, Limited Exclusion Order at 2 (Mar. 8, 2018). In his view, the majority's approach here, and in *Fitness Devices*, Inv. No. 337-TA-1265, is thus a departure from the Commission's normal practice. *See Fitness Devices*, Notice of Comm'n Determination to Reconsider the

Apple further requests that the exemption apply to infringing Apple Watches imported prior to the end of the period of Presidential review, but then purchased by customers after the end of the period of Presidential review. *See* RBr. at 81–82. The Commission denies Apple's request for this extension to the exemption. The Commission notes that, after the Presidential review period has expired, if the orders are not disapproved, Apple will not be permitted to sell infringing articles that it imported during the Presidential review period.

Accordingly, as noted above, the Commission's remedial orders include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations; and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period of Presidential review when those imports are to service and/or repair Apple Watches outside of warranty obligations. This exemption protects reasonable consumer expectations, and also mitigates potential harm to the public health and welfare by allowing research participants using infringing Apple Watches pursuant to a research study to have that device repaired or replaced such that they may be able to continue the study using the same device they started with.

iv. Apple Has Not Shown That a Delay Is Warranted

In brief, the Commission declines Apple's request that enforcement of the Commission's remedy be delayed for twelve months.

Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders, 88 Fed. Reg. 30158, at 30160 n.2 (May 10, 2023) (dissenting views of Commissioner Kearns).

a) The Parties' Arguments

Apple's Arguments

Apple requests that the Commission delay the enforcement of its remedial order so that manufacturers of the reasonable alternatives to the infringing Apple Watches (discussed above) can ramp up supply of those alternatives such that they can fill any void created by the Commission's exclusion of the infringing Apple Watches. *See, e.g.*, RBr. at 70. According to Apple, "there simply will not be enough supply to fill the massive demand gap that will result from the supply shock of an exclusion order." RBr. at 70. Apple alleges that, in addition to any ordinary difficulty in meeting demand, "the well-documented global semiconductor shortage, after-effects from COVID-19 lockdowns in China, natural disasters (including severe weather events), and delays in procuring integrated circuits and other necessary components" will further complicate matters. *Id.* at 71. Apple further argues that "[t]here is no evidence that supply can be ramped up fast enough to meet anywhere close to the entirety of consumer demand in view of the enormity of the immediate shortfall the exclusion order would create." *Id*. Apple asserts that it will take years to ramp up production to compensate for the exclusion of the Accused Products. *Id.* at 71–72. Thus, Apple requests that the Commission delay the implementation of any remedy for at least twelve months. *E.g.*, *id.* at 71–72, 89.

Complainants' Arguments

For their part, Complainants argue that the Commission should reject "Apple's unsubstantiated arguments regarding the capacity of third-party manufacturers to meet consumer demands." CBr. (Reply) at 39; *see also id.* at 39–41. Complainants further point out that Apple "fails to provide any reason it could not increase production of the Series SE, which contains virtually all the same features as the infringing products, or return to producing the Apple Watch Series 4 or 5, which also included ECG," but not blood oxygen measurements. *Id.* (citing CBr.

Ex. 93 at ¶¶ 22–24). Regarding Apple's argument related to a potential semiconductor shortage, Complainants allege that Apple overlooks that semiconductors no longer used by Apple will then become available to manufacturers of substitute products. *Id.*

b) Analysis

The Commission declines Apple's request that the Commission's remedy be delayed for twelve months. The Commission has recently considered and rejected Apple's argument in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 74–75. Moreover, like in *Wearable Electronic Devices*, Apple failed to substantiate its position that manufacturers of suitable alternative products lack the manufacturing capability to ramp up production to meet any demand. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 74–75; RBr. at 69–72. Additionally, to the extent any global events have caused any component shortages, *see* RBr. at 71, those events would affect Apple as well as other manufacturers. Accordingly, Apple has not shown any basis for the Commission to delay the effect of its remedy.

v. Conclusion

To mitigate any public health and welfare concerns, the Commission provides within its remedial orders a service, repair, and replacement exemption. *See supra* section V.B.4.a.iii. In view of the provided exemption, the Commission finds that its remedial orders will not raise any public health or welfare concerns that warrant denying Complainants a remedy. There are numerous reasonable substitutes available to users and research participants in the United States, and there is at most scant evidence that the Commission's remedial orders will have any meaningful adverse impact on medical studies in the United States. Furthermore, the public interest of supporting strong intellectual property rights further supports the Commission's conclusion. *E.g.*, *Centerset Faucets*, No. 337-TA-422, Comm'n Op. at 9; *Microfluidic Devices*,

Inv. No. 337-TA-1068, Comm'n Op. at 45–46. Additionally, Apple has shown no reason for the Commission to delay the imposition of its remedy.

b. Competitive Conditions in the United States Economy

In brief, the Commission finds that the remedial orders in this investigation will not have an adverse impact on competitive conditions in the United States economy.

i. The Parties' Arguments

Apple argues that remedial orders would harm competitive conditions in the United States economy, asserting that the Apple Watch contributes to thousands of jobs across the United States. RBr. at 86; *see also id.* at 86–87. Apple argues that "excluding the Accused Apple Watches would distort market incentives, further harming competitive conditions." *Id.* at 86 (citing RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 22–56). According to Apple, "[r]emoving a product as popular as [the] Apple Watch would lessen competition, and a sudden shortfall of smartwatches would likely yield higher prices, which would impose further harm on US consumer." *Id.* at 87 (citing RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 22–24, 46–55) (internal quotations omitted).

For their part, Complainants argue that their requested remedy would not harm competitive conditions in the United States economy, but instead would benefit those conditions. *See* CBr. at 71–75. Complainants first allege that "major companies offer[ ] substitute smartwatches" and consumers who prefer the Apple ecosystem can still purchase the Apple Watch SE. *See id.* at 72. Complainants add that, in view of the impending remedial orders, Apple has had ample time to release non-infringing versions of its products, and "legitimate design-around efforts should always be encouraged as a path to spur further innovation." *See id.* (quoting *Tivo, Inc. v. EchoStar Corp.*, 646 F.3d 869, 883 (Fed. Cir. 2011) (en banc); *see also id.* at 72–73 (citing, *inter alia*, Alliance for U.S. Startups Stmt., EDIS Doc. ID 791674, at 2

(asserting that the Commission should not support Apple's "efficient infringement"); Innovation Alliance Stmt., EDIS Doc. ID 791048, at 1 (same)). Complainants additionally assert that issuing their requested remedial orders would encourage companies to "re-shore manufacturing to the United States" and otherwise improve competitive conditions because "America's innovation economy and global competitiveness are dependent on the continued robust enforcement of inventors' intellectual property rights." *Id.* at 73 (quoting Innovation Alliance Stmt., EDIS Doc. ID 791048, at 2). Complainants add that "[h]olding Apple accountable for its 'efficient infringement' would also curtail Apple's exploitation of third parties who rely on the Apple platform." *Id.* Complainants further argue that Apple's violation of intellectual property rights "raises prices, denies consumers choice, lowers quality, and dampens the incentive of sellers of complementary, or competing products to innovate." *Id.* at 74 (quoting CFA Stmt., EDIS Doc. ID 791163, at 3). Complainants allege that allowing the continued importation of infringing Apple Watches will "give Apple an unfair competitive advantage in the narrow market for smartwatches and in the adjacent market for device ecosystems." CBr. at 74 (quoting Dinelli Stmt., EDIS Doc. ID 791686, at 4). As a result, according to Complainants, consumers are "likely to experience long term harm from reduced competition and innovation." *Id.* (quoting Dinelli Stmt., EDIS Doc. ID 791686, at 4).

ii. Non-Party Comments

Non-parties have filed comments stating that issuing remedial orders would have a positive impact on competitive conditions in the United States. *See, e.g.*, Alliance for U.S. Startups Stmt., EDIS Doc. ID 791674, at 2 (asserting that the Commission should not support Apple's "efficient infringement"); Buck Stmt., EDIS Doc. ID 791047 ("As members of Congress, it is our duty to ensure that patent laws are duly enforced, particularly when enforcement is against companies that engage in monopolistic and anti-competitive conduct.

The American public ultimately bears the cost of the monopolistic behaviors of some of the largest technology firms that, as a business model, work to consolidate market power, stifle innovation, and crush competitors."); Innovation Alliance Stmt., EDIS Doc. ID 791048, at 1 ("Vigorous enforcement and protection of intellectual property rights are essential to the competitive viability of innovative companies within the United States."); CFA Stmt., EDIS Doc. ID 791163, at 3; Dinelli Stmt., EDIS Doc. ID 791686, at 4; US Inventor Stmt., EDIS Doc. ID 791041 ("A healthy and thriving innovation ecosystem in the United States is in the public interest.").

iii. Analysis

The Commission finds, consistent with its holding in *Wearable Electronic Devices*, that its remedial orders in this investigation will not have any adverse impact on competitive conditions in the United States economy. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 79–80. As was the case in that investigation, here there are also numerous suitable alternatives to the excluded Apple Watches (as discussed above in relation to the public health and welfare public interest factor and below as to the United States consumers public interest factor).

Apple argues that the remedial orders will harm competitive conditions by jeopardizing United States jobs. *See* RBr. at 86. However, Apple does not specify how many jobs are particularly related to the infringing Apple Watches, as opposed to non-infringing Apple Watches (such as the Apple Watch SE) or researching and developing future non-infringing models, or supporting versions of the Apple Watch earlier than the Apple Watch Series 6), Apple Watch accessories (such as watch bands), or other Apple products beyond the Apple Watch altogether. *See id.* Moreover, Apple does not address whether any lost jobs due to the exclusion of the infringing Apple Watches will be counterbalanced by increased United States jobs for

manufacturers of reasonable substitutes. Apple further asserts that excluding Apple Watches would "lessen competition" and "likely yield higher prices." *Id.* at 86–87. However, as noted above and below, there is ample competition and not all Apple Watches will be excluded, as at least the Apple Watch SE would not be subject to exclusion. Thus, the Commission finds that the remedial orders in this investigation will not have any adverse impact on competitive conditions in the United States economy.

c. The Production of Like or Directly Competitive Articles in the United States

The Commission finds that its remedial orders in this investigation will not have any adverse impact on the production of like or directly competitive articles in the United States.

i. The Parties' Arguments

Apple does not contest that it does not manufacture any products in the United States. *See generally* RBr.; RBr. (Reply). Instead, Apple argues:

> The competitive harms will not be offset by substantial "production of like or directly competitive articles," 19 U.S.C. § 1337(d)(1), because Apple's primary smartwatch competitors, for example, do not manufacture their products in the United States. And while the Masimo W1 is manufactured in the United States, it is not a reasonable substitute.

RBr. at 73. Apple explains that, "[a]lthough Complainants claim that the Masimo W1 is made in the U.S., the W1 is not a smartwatch and not a reasonable substitute for smartwatch consumers who want the Accused Apple Watches." RBr. (Reply) at 44. Apple adds that, regardless, "Complainants have not described how many [W1 Watch] units are manufactured in the U.S. or how many more units it would expect to manufacture in the U.S (as opposed to its [redacted])." *Id.* Thus, according to Apple, "no evidence exists that an exclusion order would have any meaningful impact on U.S. production." *Id.*

Complainants point out that neither the Apple Watches nor any smartwatches made by Samsung, Fitbit, or Garmin are produced in the United States, but that Masimo produces its W1 Watch in the United States and [redacted] *Id.* (citing CBr. at Ex. 53 (Muhsin Decl.) at ¶ 5). Thus, according to Complainants, "the only impact an exclusion order would have on like or directly competitive articles made in the United States is that Masimo likely will be able to continue to build its domestic industry in its intellectual property because of the increased competition in the market caused by exclusion of Apple's infringing products." *Id.*

ii. Analysis

The Commission finds that the "production of like or directly competitive products in the United States" public interest factor does not weigh against the Commission's remedy in this investigation. As the parties appear to agree, neither the Apple Watch nor smartwatches made by Samsung, Fitbit, or Garmin are produced in the United States. *See* CBr. at 75; RBr. at 73. Moreover, there is no evidence suggesting that any reasonable substitute for excluded Apple Watches, aside from Masimo's W1 Watch or Freedom Watch, [redacted] *See, e.g.*, CBr. at 75; RPHBr. at 251–52 (disputing only the extent that Masimo's domestic facilities are used for production of the W1 Watch); RBr. (Reply) at 45 (asserting only that Complainants did not identify how many units it has produced or plans to produce in the United States).

And as for the W1 Watch and Freedom Watch, Complainants do not provide quantitative evidence regarding the extent of any United States production of these watches or the extent that potential customers would choose Masimo's W1 Watch or Freedom Watch as a substitute for excluded Apple Watches. Therefore, the Commission cannot assess the extent to which Complainants' requested remedial orders would result in increased domestic production of

suitable substitutes to the excluded Apple Watches. However, based on the absence of domestic production of excluded products, the remedial orders in this investigation will not have an adverse impact on the production of like or directly competitive articles.

d. United States Consumers

In brief, in view of the exemption for service, repair, and replacement (discussed above), any effect of the Commission's remedial orders on United States consumers does not rise to the level of a public interest concern.

i. The Parties' Arguments

Apple argues, that "[b]eyond the potential effects on the health of U.S. consumers, an exclusion order would further harm those consumers by impeding access to the valuable, tightly integrated suite of features that drive demand for these devices." RBr. at 85. According to Apple, "[m]illions of Americans rely on [the] Apple Watch to stay connected, and in addition to the Blood Oxygen feature at the heart of this Investigation and the health features described above, [the] Apple Watch also contains a complement of features consumers enjoy—including productivity, payment, navigation, safety, and accessibility functions." *Id.* Apple then declares that "[a]n exclusion order would take those features out of the hands of American consumers." *Id.* at 86.

For their part, Complainants argue that their requested remedy would benefit United States consumers by removing Apple's alleged poor-performing blood oxygen feature from the marketplace while not interfering with their access to non-infringing Apple Watches. *See* CBr. at 75. Complainants further argue that consumers would benefit "in the long run by encouraging investment in the next generation of healthcare innovation." *Id.* Complainants additionally urge the Commission to reject any argument that remedial orders should be denied based on the widespread use of the Apple Watch. *Id.* at 75–76 (citing MDMA Stmt., EDIS Doc. ID 791167,

at 4 (declaring that "[t]hat would be tantamount to arguing if you can infringe in a huge way, then you should escape the consequences"); C4IP Stmt., EDIS Doc. ID 791567, at 3–4 (similar)). Complainants then assert that "many consumers desire to have an Apple Watch only because of the benefits of having multiple devices within Apple's device ecosystem," and "[c]onsumers would benefit by expanding their choices to other device makers and those that choose to continue using Apple devices still would be able to select non-infringing Apple Watches like the SE." *Id.* at 76 (citing Dinielli Stmt., EDIS Doc. ID 791686, at 3).

ii. Non-Party Comments

Non-parties filed submissions commenting on the United States consumers public interest factors both in support of Complainants and Apple. *See, e.g.*, Dinelli Stmt., EDIS Doc. ID 791686, at 4 (declaring that allowing Apple to import infringing Apple Watches would give Apple an unfair competitive advantage and will likely cause United States consumers "long term harm from reduced competition and innovation"); Saxon Comments, EDIS Doc. ID 797811 (asserting that consumers benefit from having "more accurate tools, not fewer . . . to help identify cardiac ailments").

iii. Analysis

In view of the exemption for service, repair, and replacement (discussed above), any effect of the Commission's remedial orders on United States consumers does not rise to the level of a public interest concern.

First, there are numerous reasonable substitutes for the infringing Apple Watches available to United States consumers. Looking beyond the public health and wellness aspects of the Apple Watch (as those are considered separately in the public health and welfare public interest factor, discussed above in section V.B.4.a.), the scope of reasonable substitutes includes general purpose smartwatches. *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op., at 85

("The correct assessment . . . for 'reasonable substitutes for the devices subject to the exclusion order,' [is] not whether 'every consumer cannot obtain the exact device desired.'" (quoting *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm. Op. at 120) (citing *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 9)). Thus, United States consumers have as reasonable substitutes at least the Apple Watch SE, the Samsung Galaxy Watch, and the Google Pixel Watch. Second, to reduce the impact of the remedial orders on United States consumers, the Commission has provided a service, repair, and replacement exemption. *See supra* section V.B.4.a.iii. Accordingly, any impact of the Commission's remedial orders on United States consumers will not rise to the level of a public interest concern.

5. Conclusion

In accordance with its statutory duty, the Commission has considered the effect of its remedial orders "upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, [and whether] it finds that such articles should not be excluded from entry." 19 U.S.C. §§ 1337(d)(l), (f)(1). To prevent any harm from the remedial orders to the public health and welfare and to United States consumers, the Commission's LEO and CDO each include an exemption for service, repair, and replacement. *See supra* section V.B.4.a.iii. As in *Wearable Electronic Devices*, this exemption mitigates potential harm to the public health and welfare by allowing research participants using infringing Apple Watches pursuant to a research study to have that device serviced and repaired or have it replaced, if it is under warranty, such that they may be able to continue the study using the same device they started with. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 70–71, 80–81. Additionally, Apple has not shown any reason why the Commission should delay the enforcement of its remedy.

C. Bonding

As discussed below, the Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

1. The Applicable Law

If the Commission enters an exclusion order or a CDO, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm'n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a one hundred percent (100%) bond. *See, e.g.*, *Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6–7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006).

2. The RD

Before the ALJ, Complainants sought a bond in the amount of 100 percent of the entered value of the Accused Products because the accused Apple Watch products are allegedly "harming the public's perception of pulse oximetry." RD at 5 (quoting CPHBr. at 312 and citing CPHBr. (Reply) at 182–83). For its part, Apple argued that a zero percent bond is appropriate because Complainants have not identified any domestic industry products that compete with the Accused Products. *Id.* (citing RPHBr. at 280). Apple further argued that Complainants' theory of harm to public perception is unsubstantiated and is, in any event, not an appropriate basis for requiring a bond. *Id.* (citing RPHBr. at 280–81; RPHBr. (Reply) at 175–76).

The RD found that Complainants did not meet their burden of establishing the need for a bond. RD at 6. The RD pointed out that Complainants did not argue that a bond is needed to protect any of its own competing products during the period of Presidential review. *Id.* (citing CPHBr. at 312). The RD further pointed out that Complainants did not present any evidence or argument regarding (1) the pricing (or expected pricing) of any such competing product; (2) the possibility (or impossibility) of performing a price differential analysis based on any such pricing; or (3) any reasonable royalty analysis. *Id.* at 6 n.5 (citing CPHBr. at 312; CPHBr. (Reply) at 182–83; *Certain Network Devices, Related Software & Components Thereof (II)*, Inv. No. 337-TA-945, Comm'n Op., 2017 WL 3614521, at *75 ("*Network Devices (II)*"). The RD further observed that, at the time of the hearing, the W1 Watch was not available for sale to consumers on the open market. *Id.* at 6 (citing, *inter alia*, Tr. (Kiani) at 179:17–22). The RD additionally declared that Complainants' alleged harm to the "the public's perception of pulse oximetry" based on the alleged inaccuracy of the Apple Watch's pulse oximetry measurements is not an appropriate basis for setting a bond because the "purpose of bonding is to protect complainants from injury—not to remedy harms to public perception." *Id.* The RD further

added that "[i]t is not clear from the record that the alleged harm to public perception causes injury to Complainants." *Id.* The RD additionally declared that "Complainants also have identified no clear evidence of current competition between the Apple Watch and Masimo rainbow® sensors." *Id.* at 6 n.7 (citing, *inter alia*, CPHBr. at 312). Thus, the RD found that Complainants have failed to establish the need for a bond. *Id.* at 7.

3. The Parties' Arguments

Before the Commission, Complainants again request that the Commission require bond to "protect Masimo from the detrimental impact of Apple's continued importation of infringing Apple Watches that do not reliably measure oxygen saturation." CBr. at 87 (citing CX-1616, CX-1293, CX-1606). Regarding an alleged competitive injury, Complainants rely on purported concessions by Apple that (1) it, like Complainants, sell "direct-to-consumer devices that measure wellness parameters (including blood oxygen)" and (2) it acknowledged that "Masimo plans to launch a product that competes directly with the Apple Watch later this year." *Id.* (citing Respondent's Motion to Preclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), EDIS Doc. ID 750872, at 4, 11 (Sept. 2, 2021)). Complainants additionally assert that they will be injured by a lack of bond because of the "competitive status of the parties," citing a Delaware litigation in which Apple's financial expert described Masimo's "ongoing and escalating sales of W1," "Masimo's serious and long-term intentions to pivot into the smartwatch segment," and Masimo's access to 20,000 points of distribution for the W1. CBr. (Reply) at 50 (citing CBr. (Reply) at Ex. 91 at 33, 36, 37).

For its part, Apple supports the RD's recommendation that bond be set at zero percent. *See* RBr. at 91–92. Apple asserts that "Complainants have not met their burden of establishing the need for a bond," *id.* at 91 (quoting RD at 6), reasoning that Complainants failed to identify

any domestic industry products that "compete with the accused Apple Watch products" and to "present any argument concerning pricing of competing products or reasonable royalty analysis," *id.* (citing RD at 6 & n.5; *Certain Elec. Devices, Including Wireless Comm'n. Devices, Portable Music & Data Processing Devices, and Tablet Computs.*, Inv. No. 337-TA-794, Comm'n Op. at 118–19 (July 5, 2013); *Network Devices (II)*, Inv. No. 337-TA-945, Comm'n Op. at 129–30). Apple further agrees with the RD that the alleged harm to the public perception of pulse oximetry is not a proper basis for justifying bond. *Id.* (citing RD at 6–7). Apple adds that, at the time of the hearing, Complainants did not have a competing product available for sale to consumers in the United States on the open market. *Id.* at 92 (citing RD at 6). Apple further contests that the Apple Watches cause harm to the consumer perception of pulse oximetry. *See* RBr. (Reply) at 47–48. Apple asserts that Complainants' assertion is based on "non-scientific news media articles" and "was addressed at the hearing and thoroughly debunked during the cross-examination of Complainants' economic expert, who conceded that his opinion on 'harm to consumer perception' was not based on testing or technical expert testimony." *Id.* (citing, *inter alia*, CX-1616, CX-1293, CX-1606; Tr. (McGavock[73]) at 552:22–553:14). Apple adds that the "accuracy and reliability of the Blood Oxygen feature on Apple Watch is well documented." *Id.*

4. Analysis

The Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles

[73] Daniel McGavock is Complainants' expert witness, who was admitted as an expert in financial matters, offering testimony regarding economic domestic industry, bond, and commercial success. *E.g.*, Final ID at 6.

subject to the LEO. The Commission agrees with the RD that the alleged harm to the public's perception of pulse oximetry is not a cognizable basis for establishing the need for bond and has nevertheless not been substantiated as causing any harm (quantifiable or otherwise) to Complainants. *See* RD at 6. The Commission additionally agrees with the RD that Complainants have not shown any basis for supporting any specific bond based on pricing information or reasonable royalty rates. *See, e.g.*, RD at 5; *Microsphere Adhesives*, Inv. No. 337-TA-366, Comm'n Op. at 24 (basing bond on price differential when such information is available); *Audio Digital-to-Analog Converters*, Inv. No. 337-TA-499, Comm'n Op. at 25 (relying on a reasonable royalty analysis when pricing information was not available). Complainants' vague assertions as to the "competitive status of the parties" (*see* CBr. (Reply) at 50) are insufficient to establish a bond amount sufficient to protect Complainants from any injury during the period of Presidential review. Accordingly, the Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

VI. CONCLUSION

The Commission has considered all of the other arguments by the parties and does not find them persuasive. Therefore, for the reasons set forth herein, the Commission determines that Complainants have established a violation of section 337 by Apple with respect to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, but not with respect to claim 12 of the '501 patent and claims 9 and 27 of the '745 patent. Accordingly, the investigation is terminated with a finding of a violation of section 337. The Commission determines that the appropriate remedy is an LEO and a CDO to Apple; that the public interest does not preclude that remedy; and the bond during the period of Presidential review is set at zero percent (*i.e.*, no bond) of the entered value.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: November 14, 2023

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF **Inv. No. 337-TA-1276**

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served upon the following parties as indicated, on **October 27, 2023**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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United States Patent and Trademark Office

May 18, 2021

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF:

U.S. PATENT: ***10,912,501***

ISSUE DATE: ***February 09, 2021***

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

R GLOVER
Certifying Officer


US010912501B2

(12) **United States Patent**
Poeze et al.

(10) **Patent No.: US 10,912,501 B2**
(45) **Date of Patent: *Feb. 9, 2021**

(54) **USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER**

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita, CA (US); **Marcelo Lamego**, Cupertino, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Cristiano Dalvi**, Lake Forest, CA (US); **Hung Vo**, Fountain Valley, CA (US); **Johannes Bruinsma**, Opeinde (NL); **Ferdyan Lesmana**, Irvine, CA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Greg Olsen**, Lake Forest, CA (US)

(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/031,356**

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(51) **Int. Cl.**

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A61B 5/145	(2006.01)
A61B 5/00	(2006.01)

(52) **U.S. Cl.**
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(Continued)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14546; A61B 5/6838; A61B 5/6816; A61B 5/6829;
(Continued)

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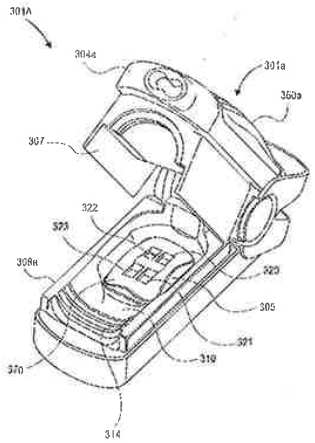
(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

30 Claims, 65 Drawing Sheets



Related U.S. Application Data

No. 16/725,292, filed on Dec. 23, 2019, now Pat. No. 10,624,564, which is a continuation of application No. 16/534,949, filed on Aug. 7, 2019, now Pat. No. 10,588,553, which is a continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a continuation of application No. 16/261,326, filed on Jan. 29, 2019, now Pat. No. 10,292,628, which is a continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a division of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, now abandoned, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, said application No. 12/829,352 is a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516.

(60) Provisional application No. 61/086,060, filed on Aug. 4, 2008, provisional application No. 61/086,108, filed on Aug. 4, 2008, provisional application No. 61/086,063, filed on Aug. 4, 2008, provisional application No. 61/086,057, filed on Aug. 4, 2008, provisional application No. 61/091,732, filed on Aug. 25, 2008, provisional application No. 61/078,228, filed on Jul. 3, 2008, provisional application No. 61/078,207, filed on Jul. 3, 2008.

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CPC . A61B 5/6843; A61B 5/6826; A61B 5/14551; A61B 5/14552; A61B 5/14532; A61B 2562/046; A61B 2562/04; A61B 2562/0233; A61B 2562/146
See application file for complete search history.

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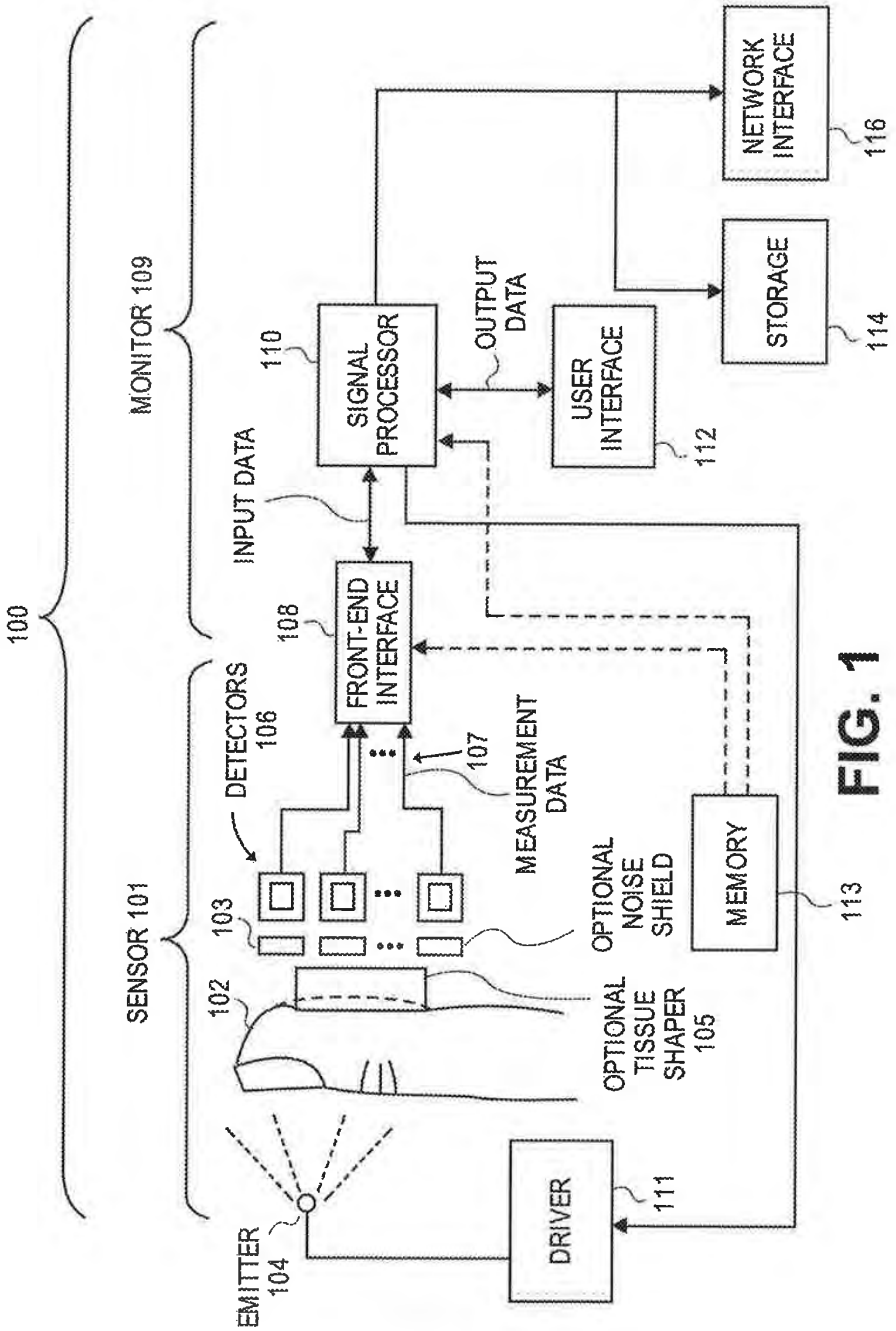


FIG. 1

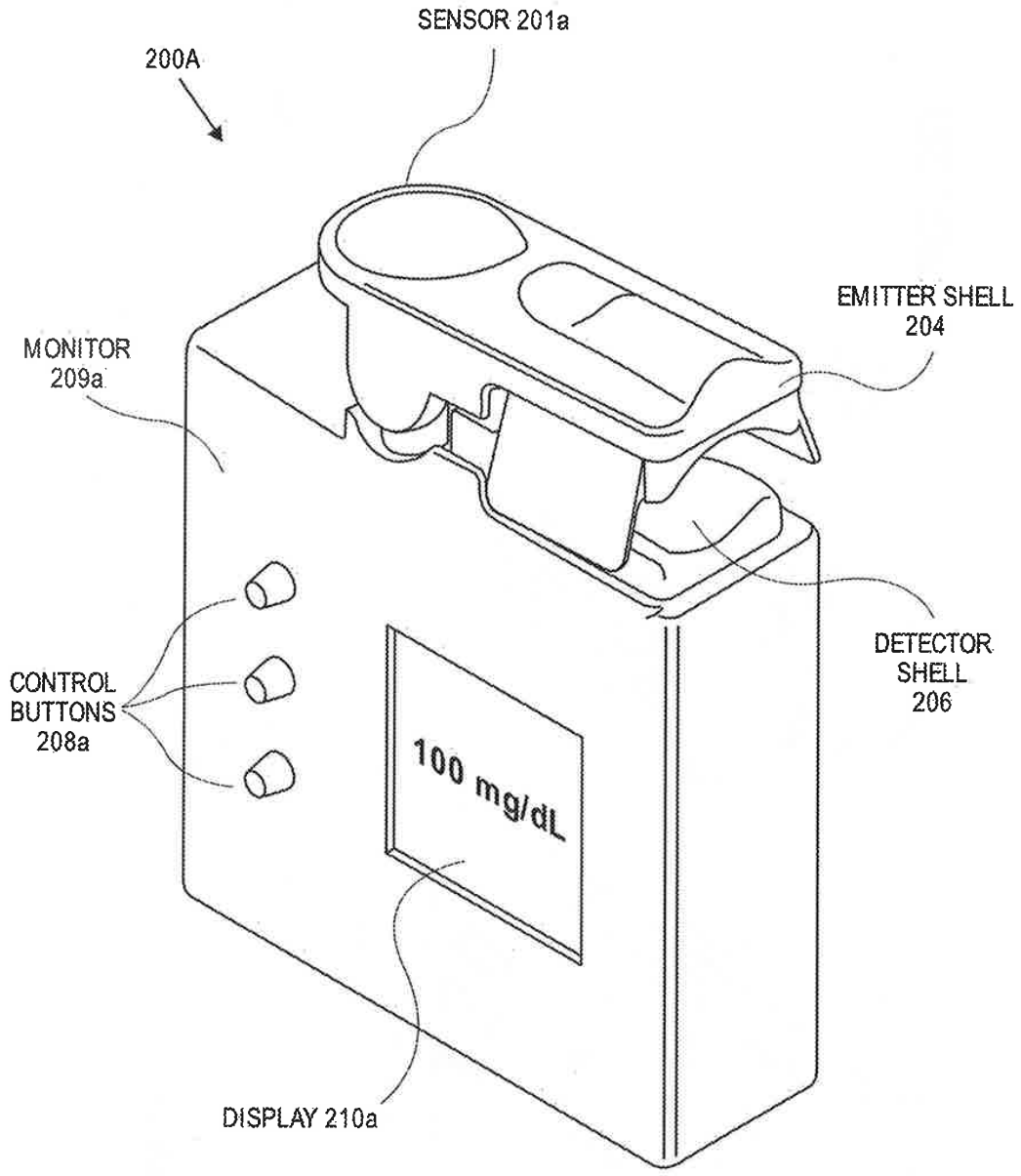


FIG. 2A

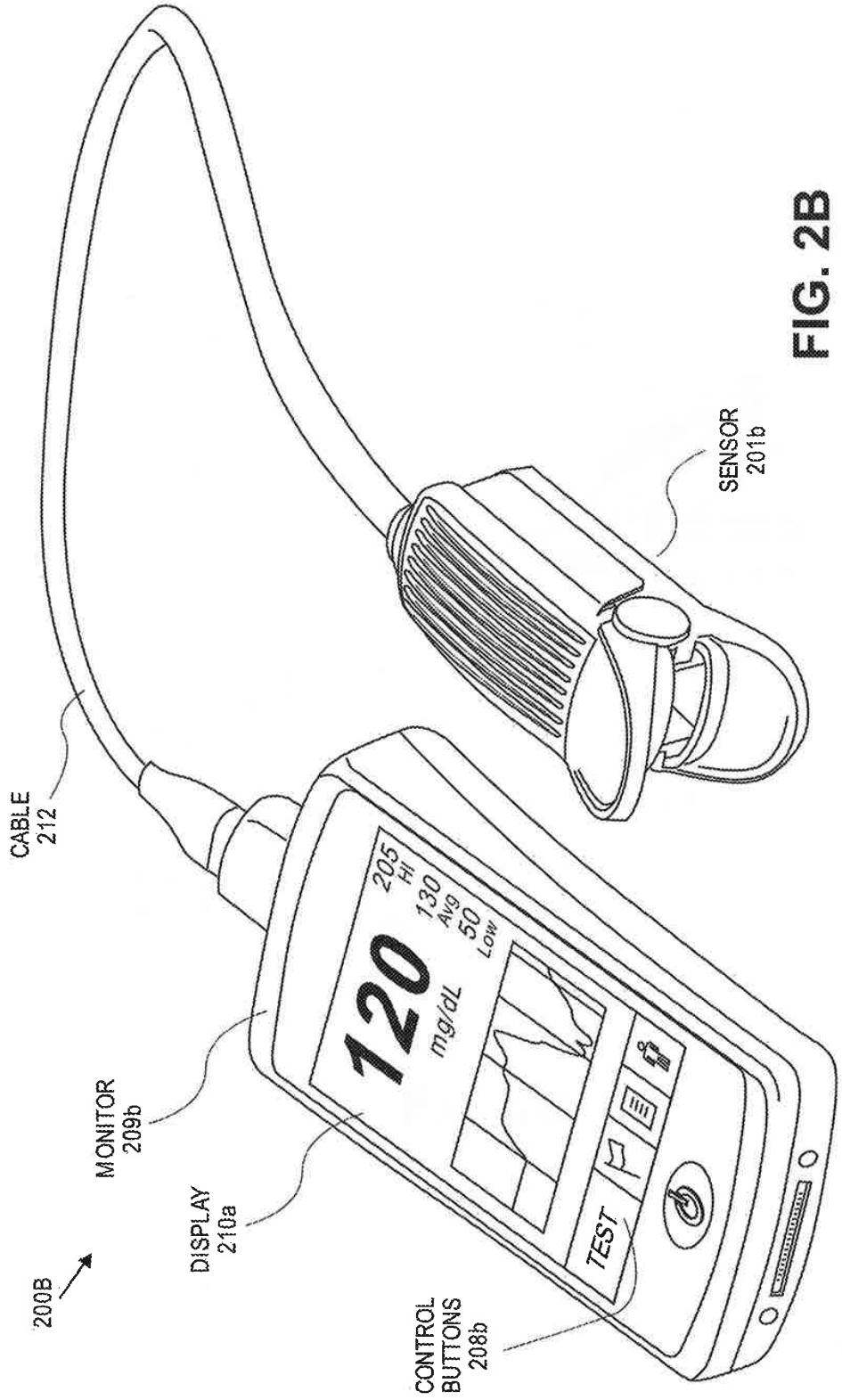


FIG. 2B

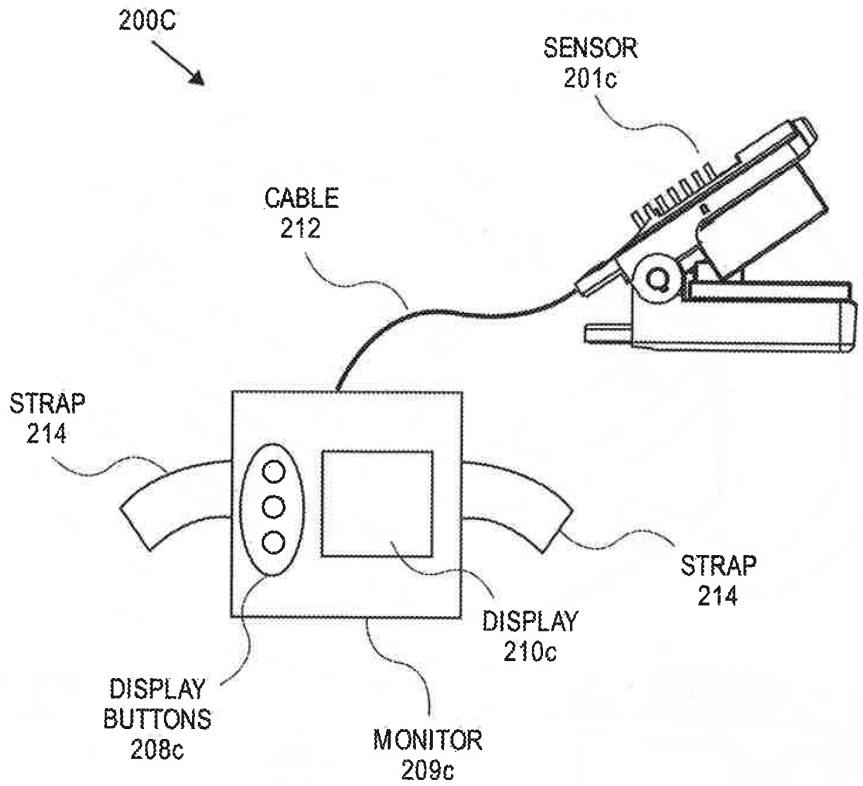


FIG. 2C

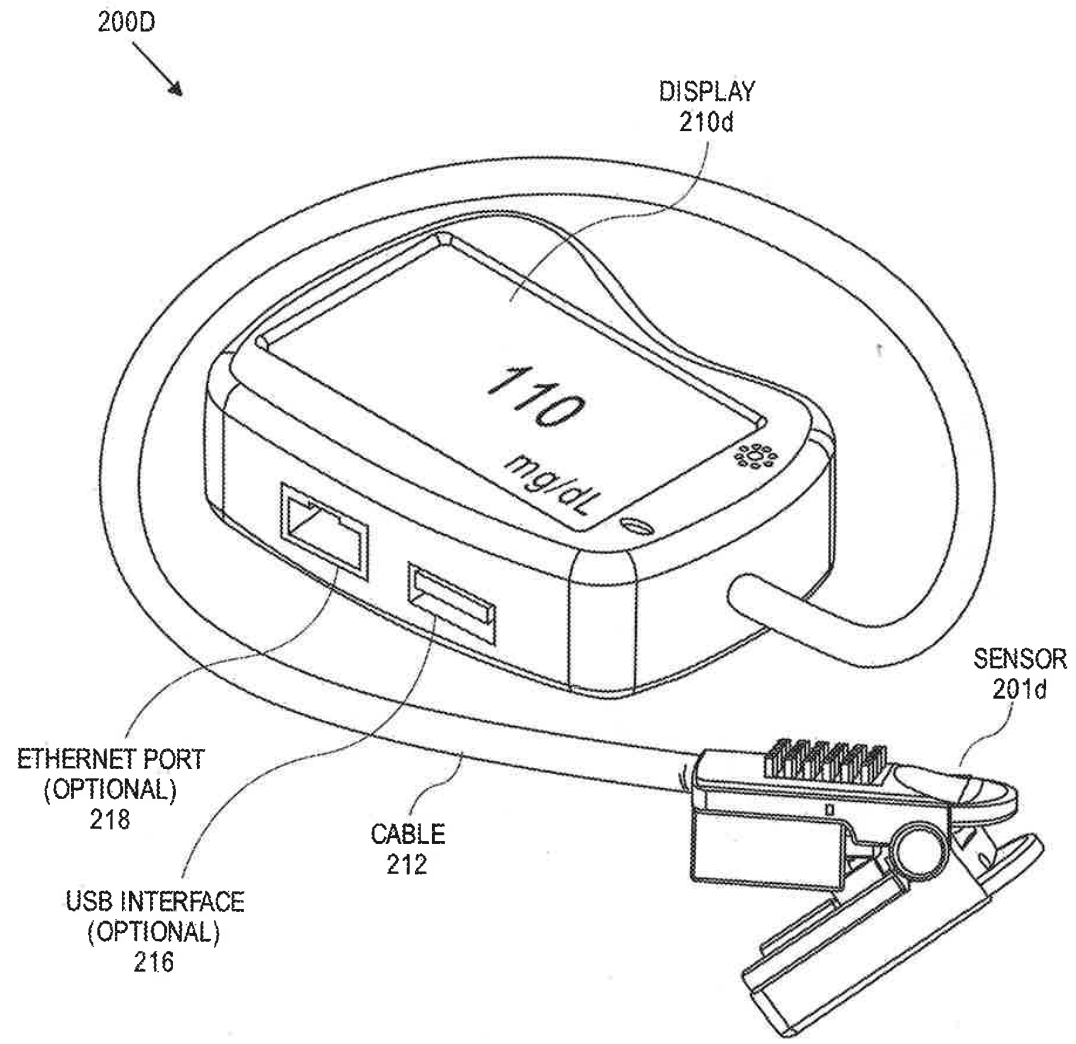


FIG. 2D

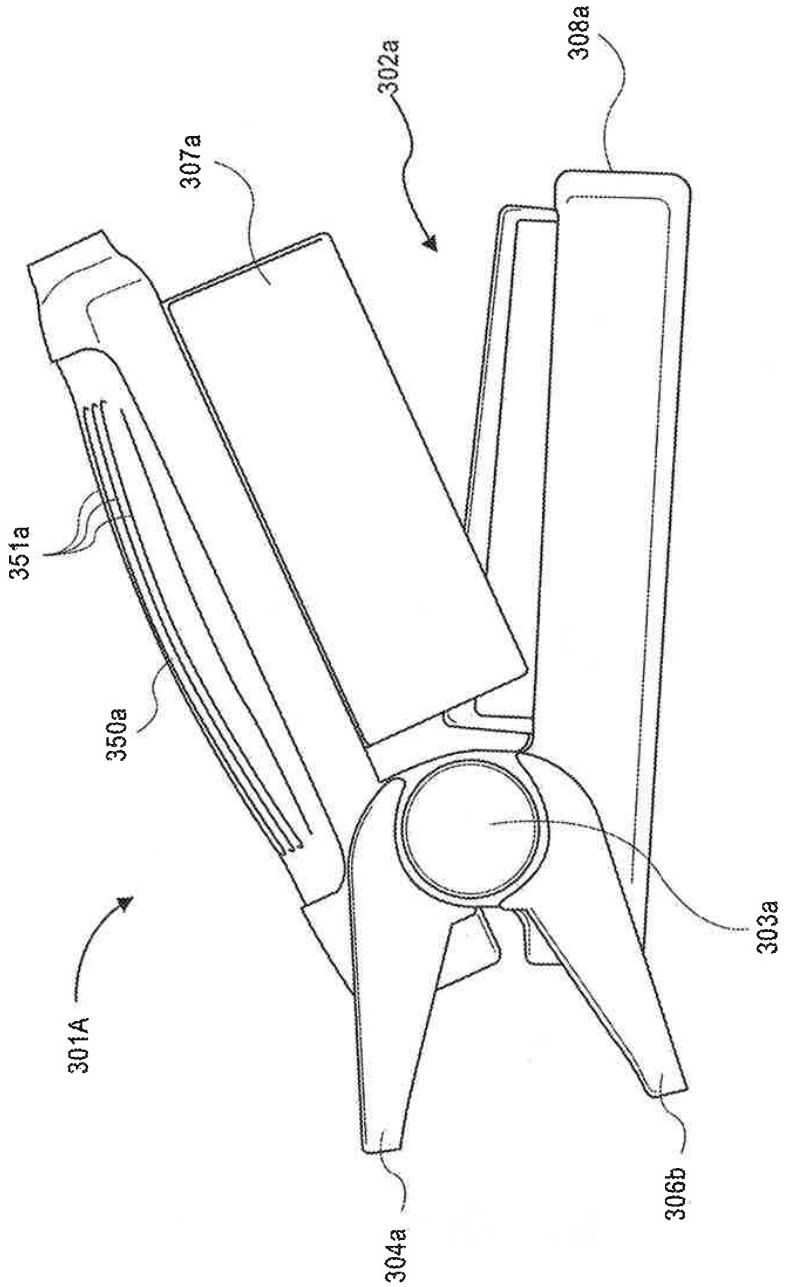
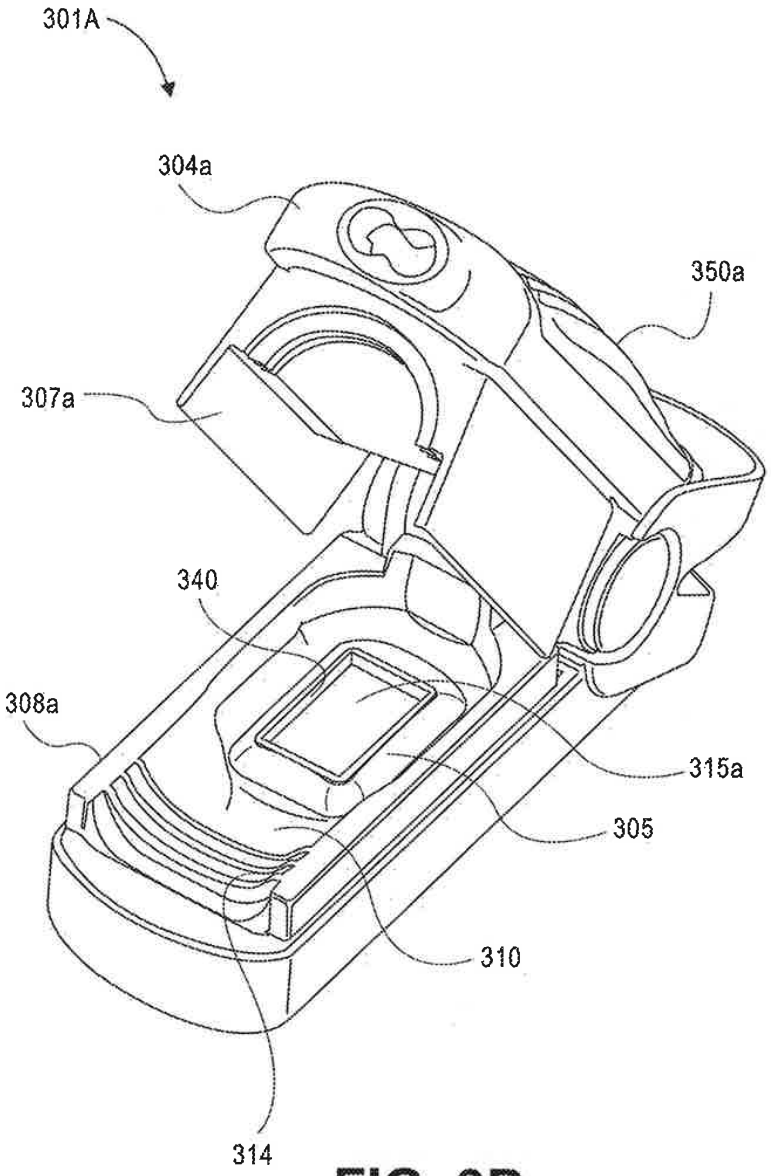


FIG. 3A



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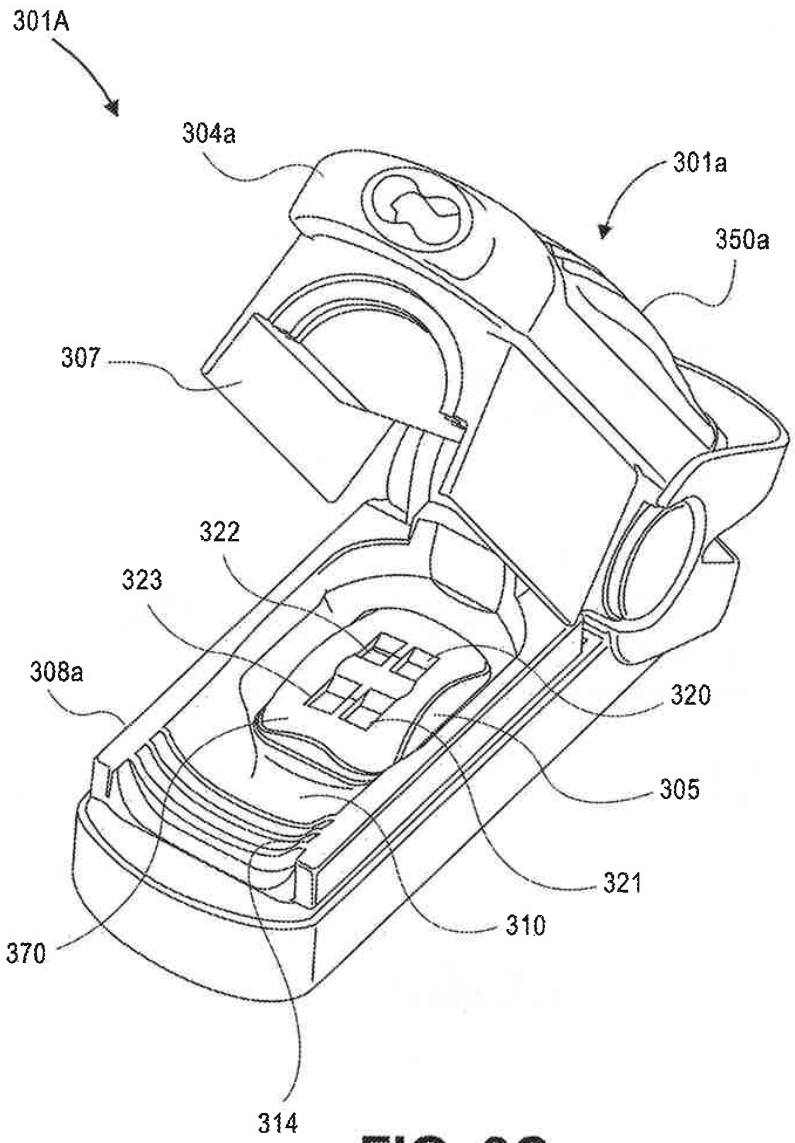


FIG. 3C

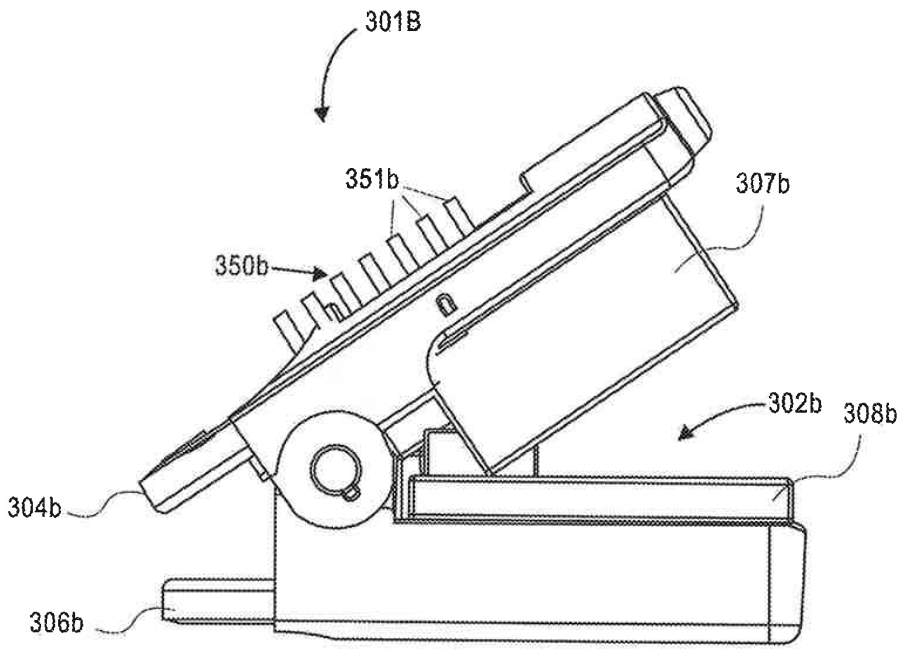
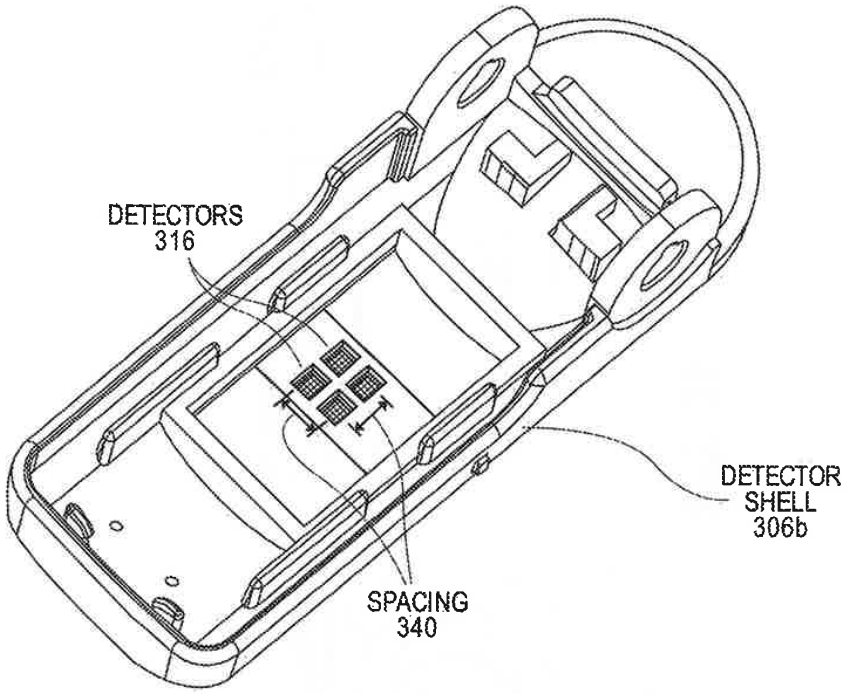


FIG. 3D



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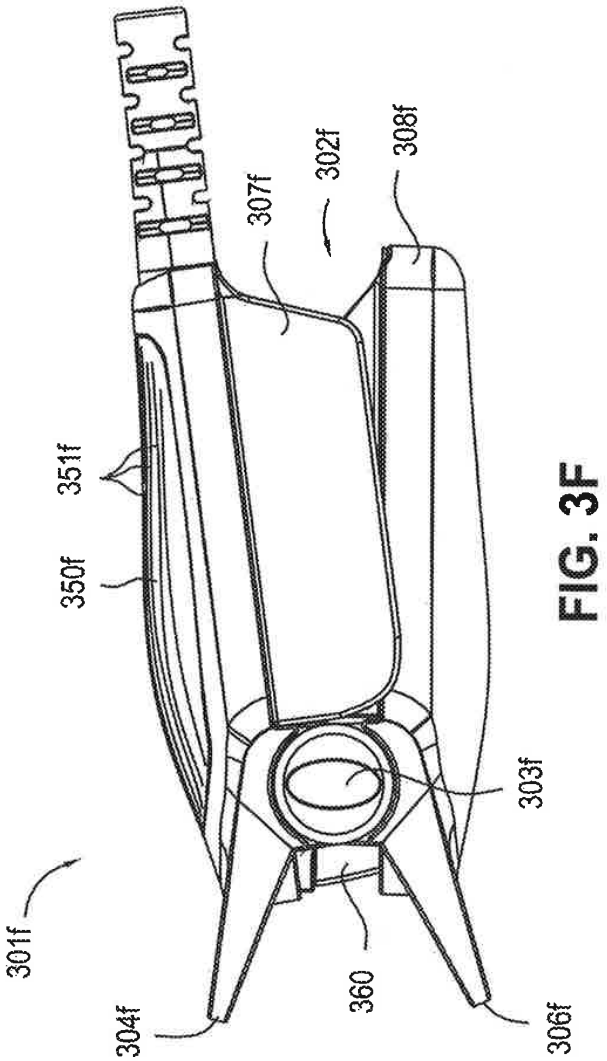


FIG. 3F

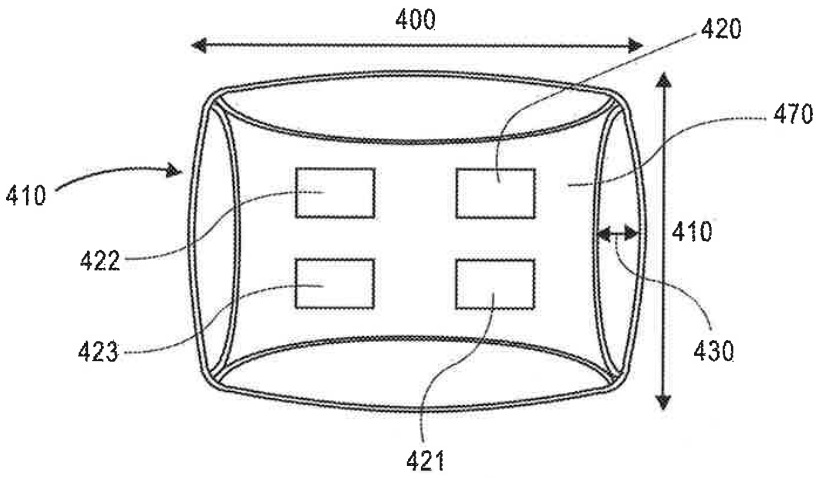


FIG. 4A

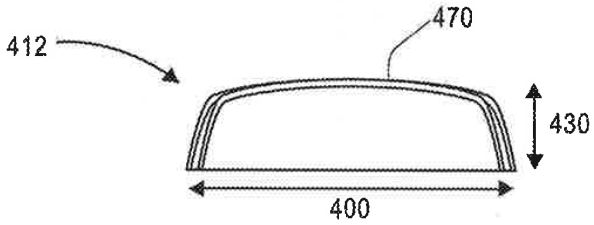


FIG. 4B

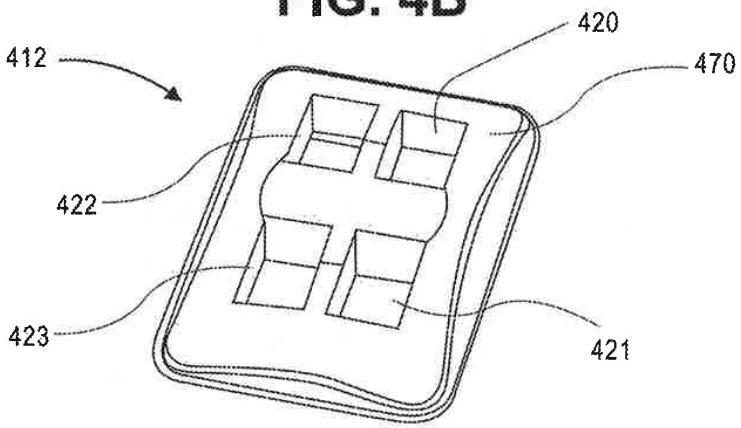


FIG. 4C

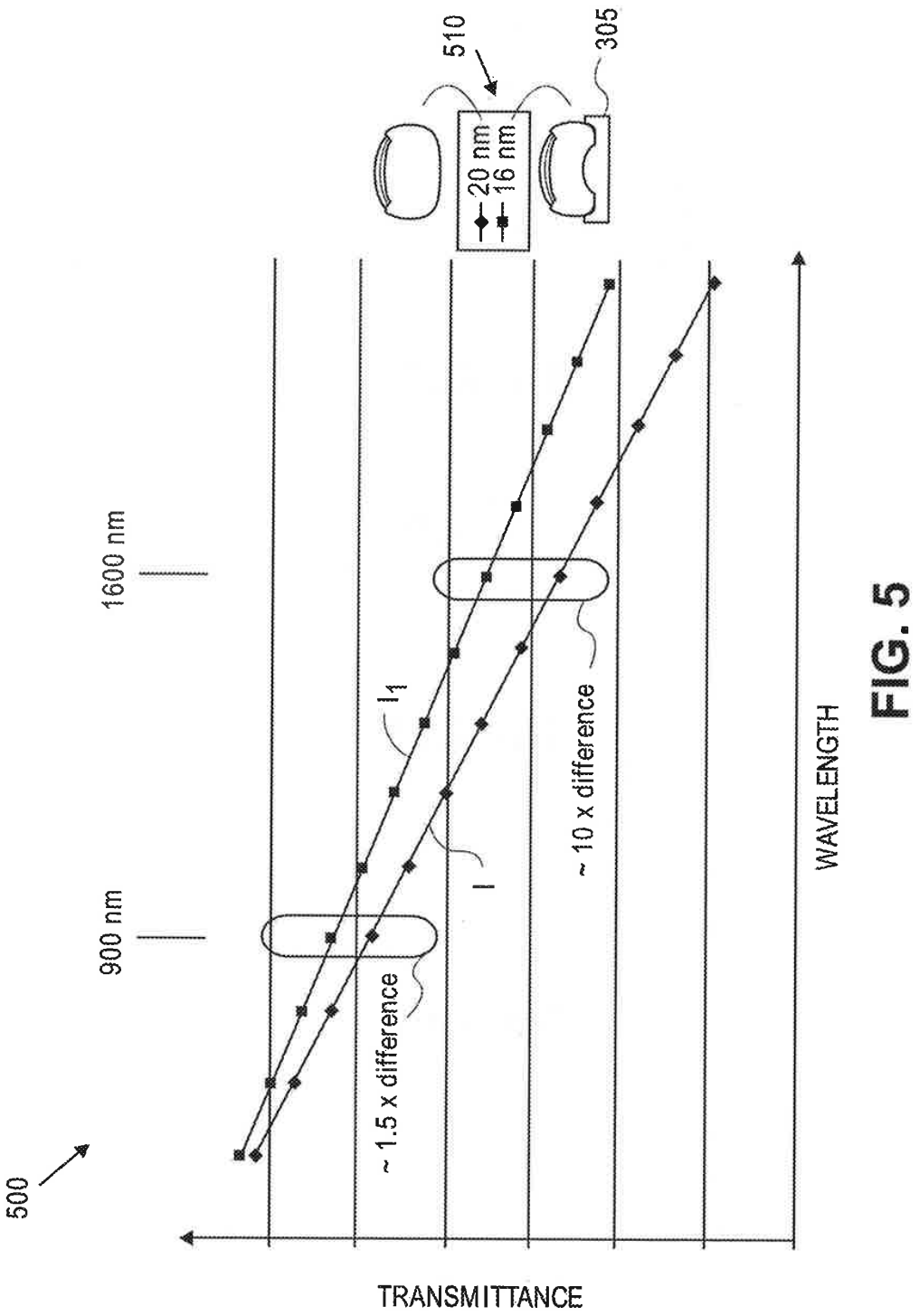


FIG. 5

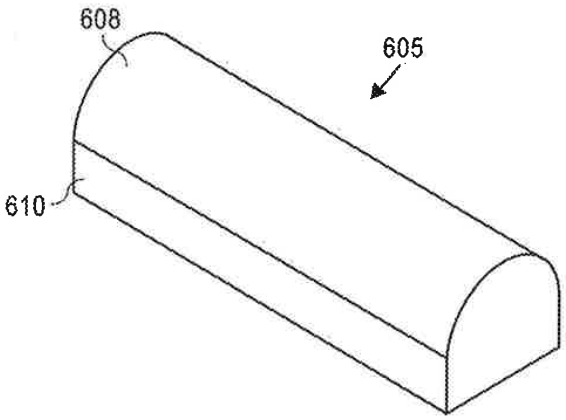
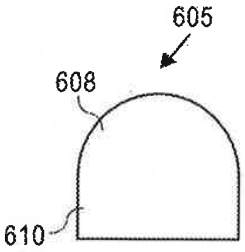


FIG. 6A



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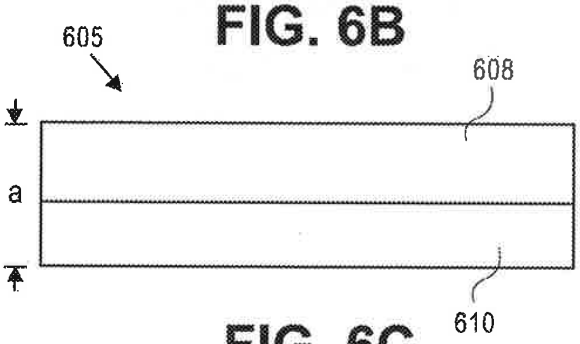


FIG. 6C

FIG. 6D

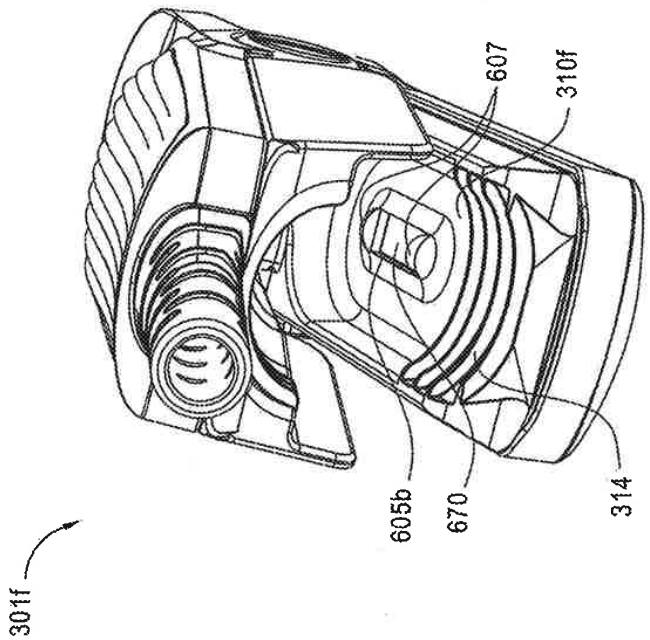
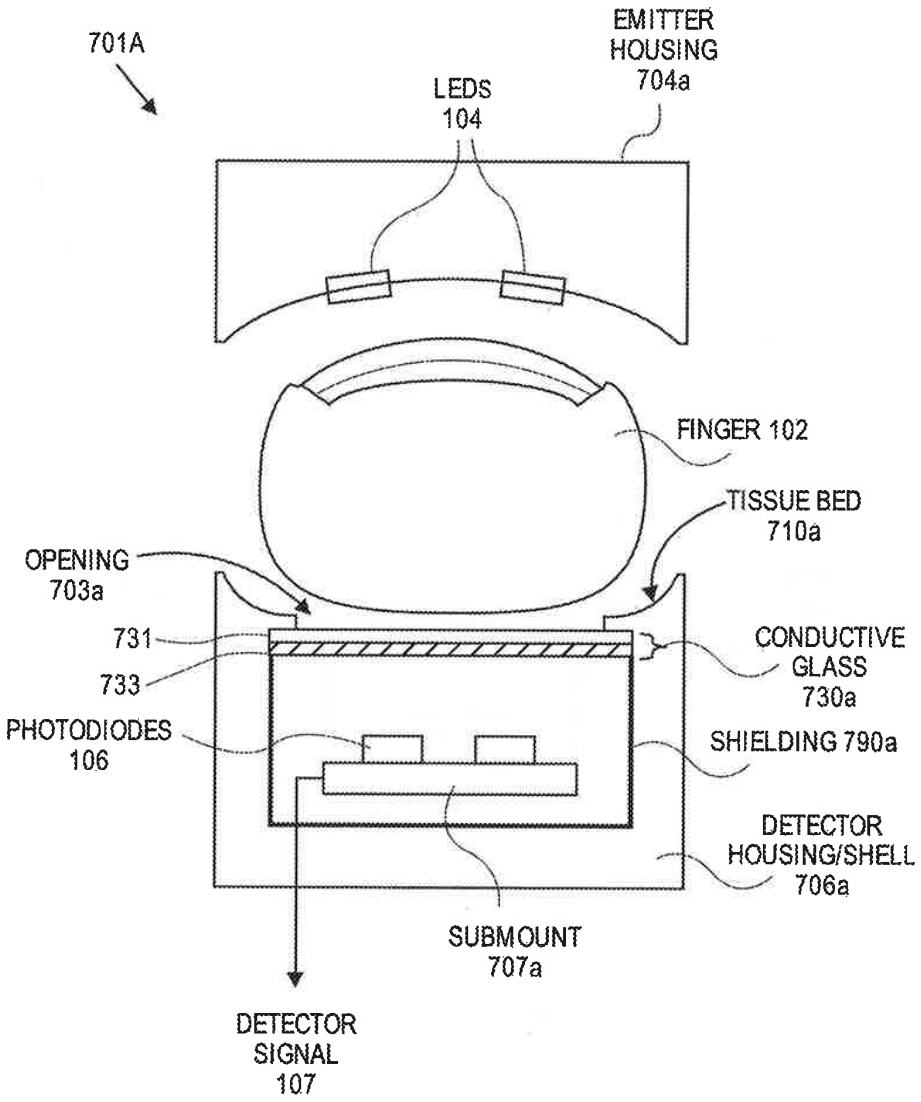


FIG. 6E



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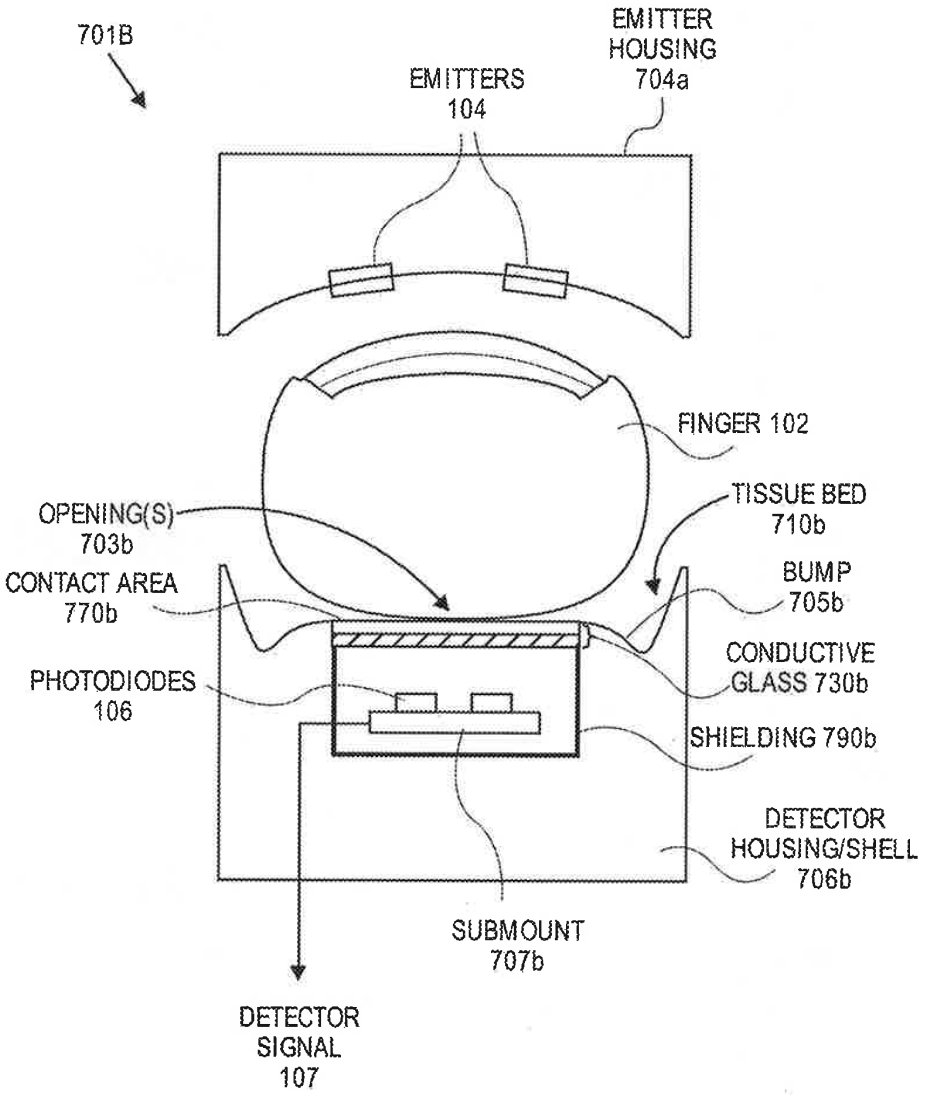

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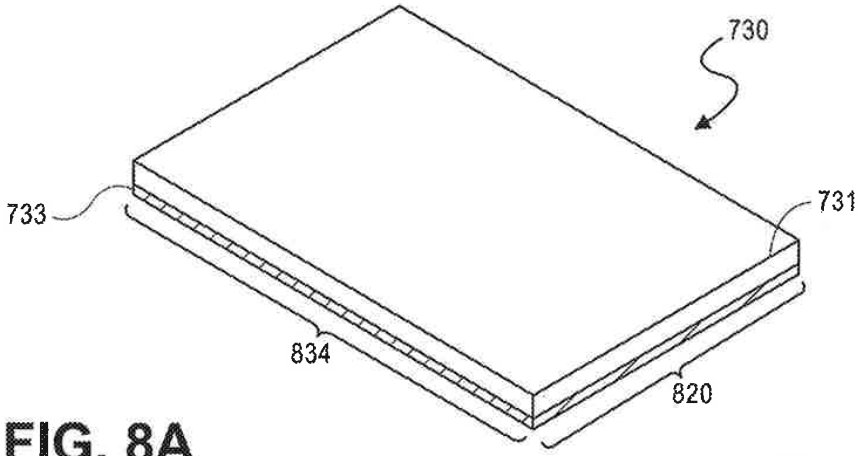

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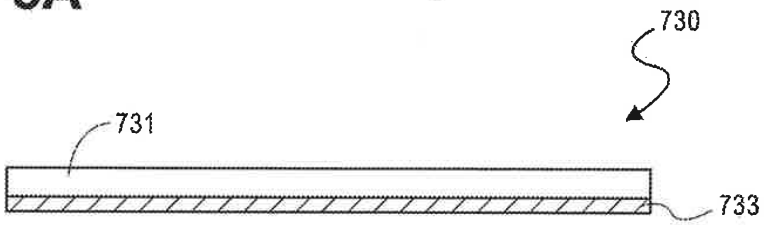

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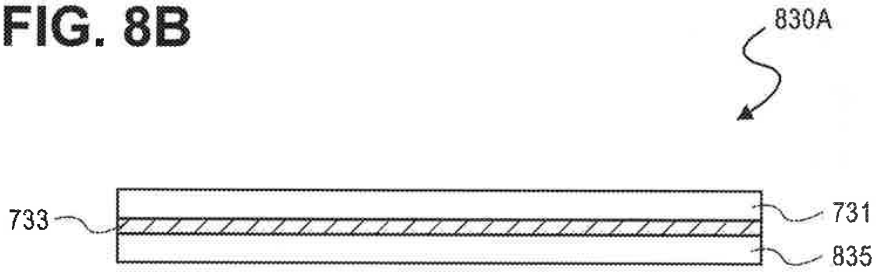

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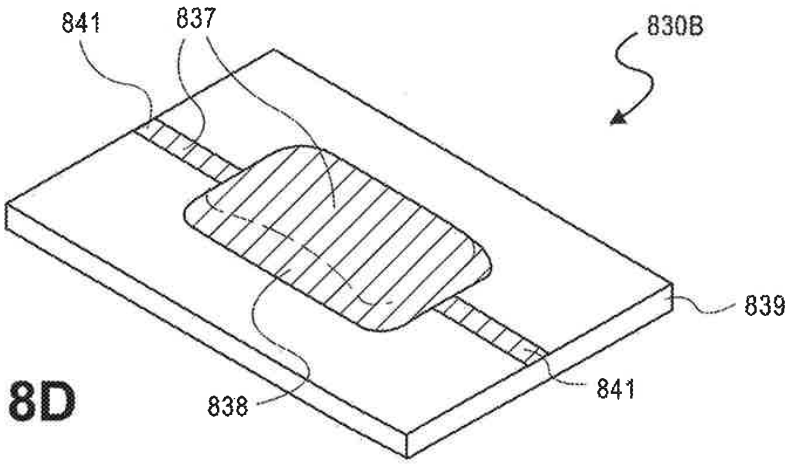

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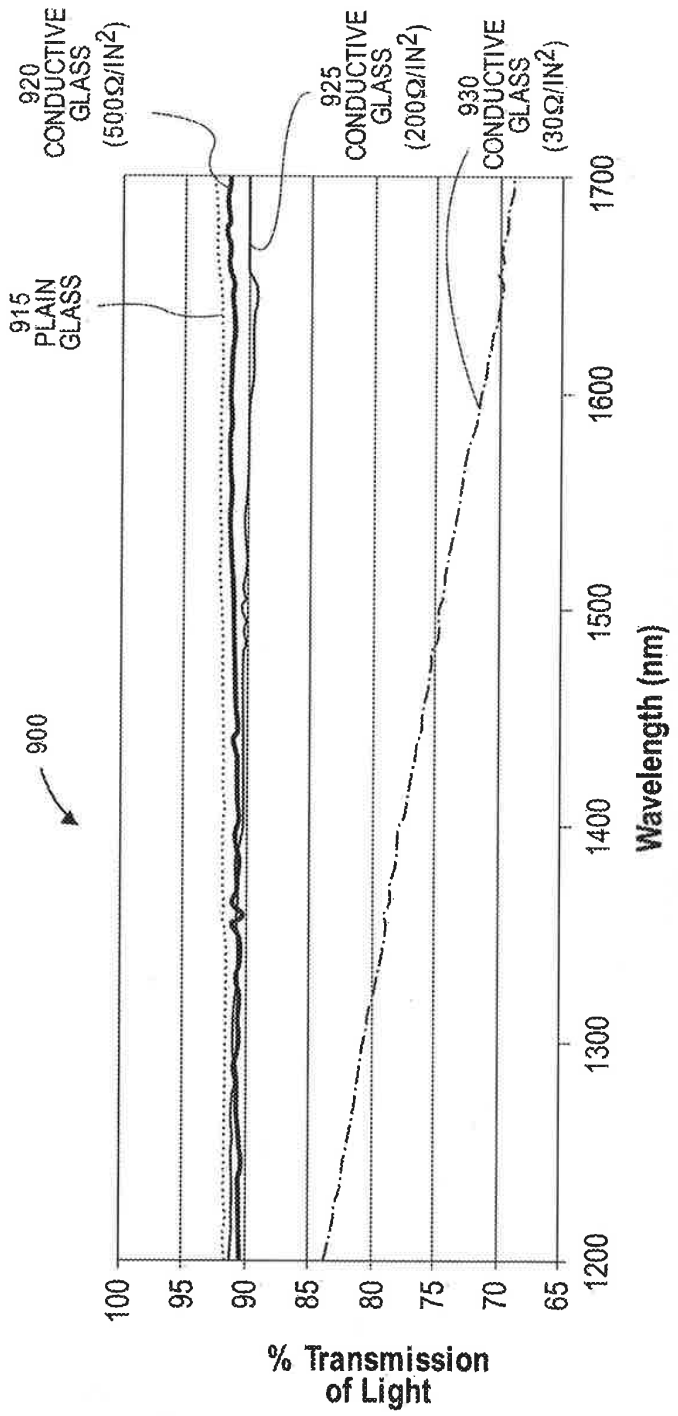
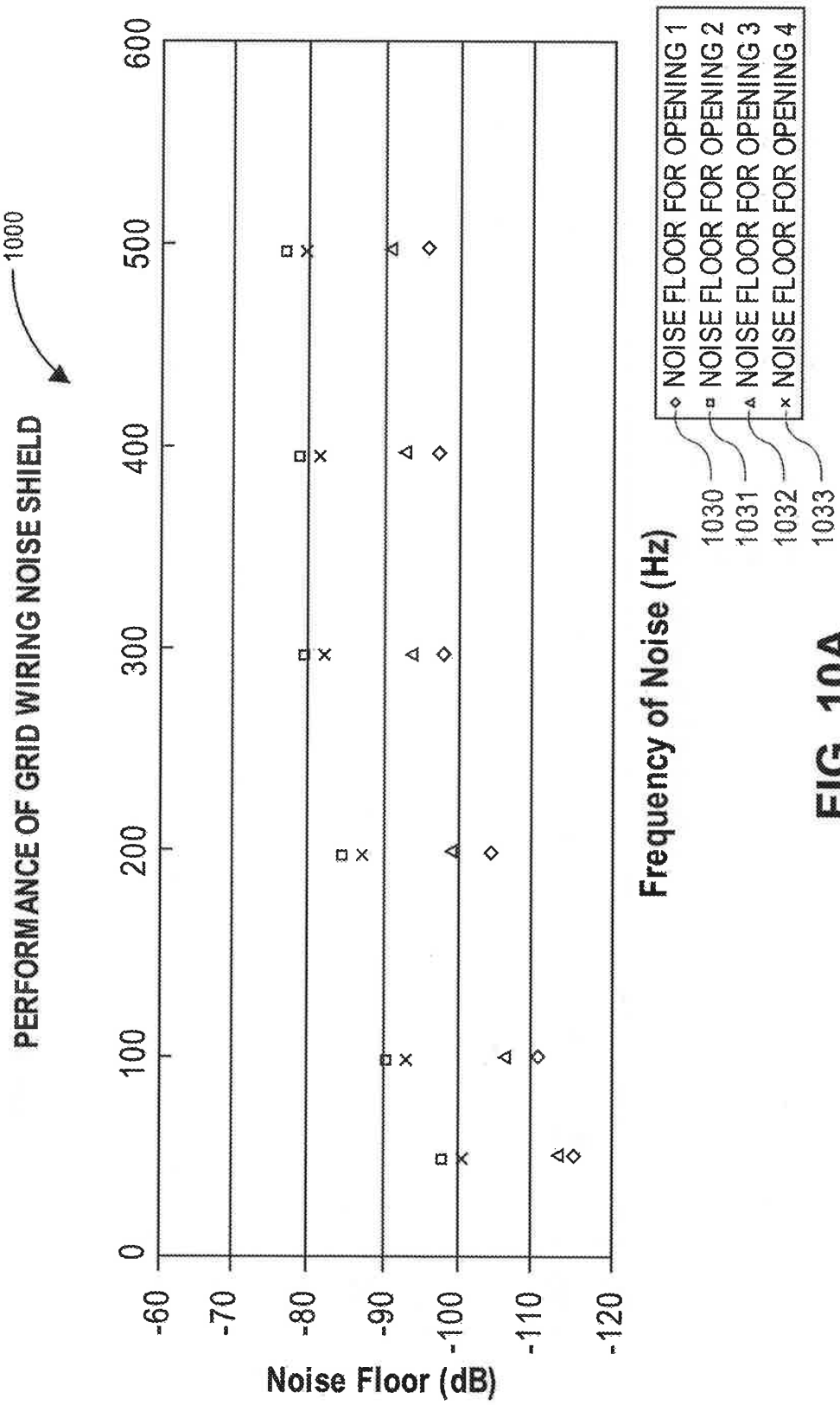


FIG. 9



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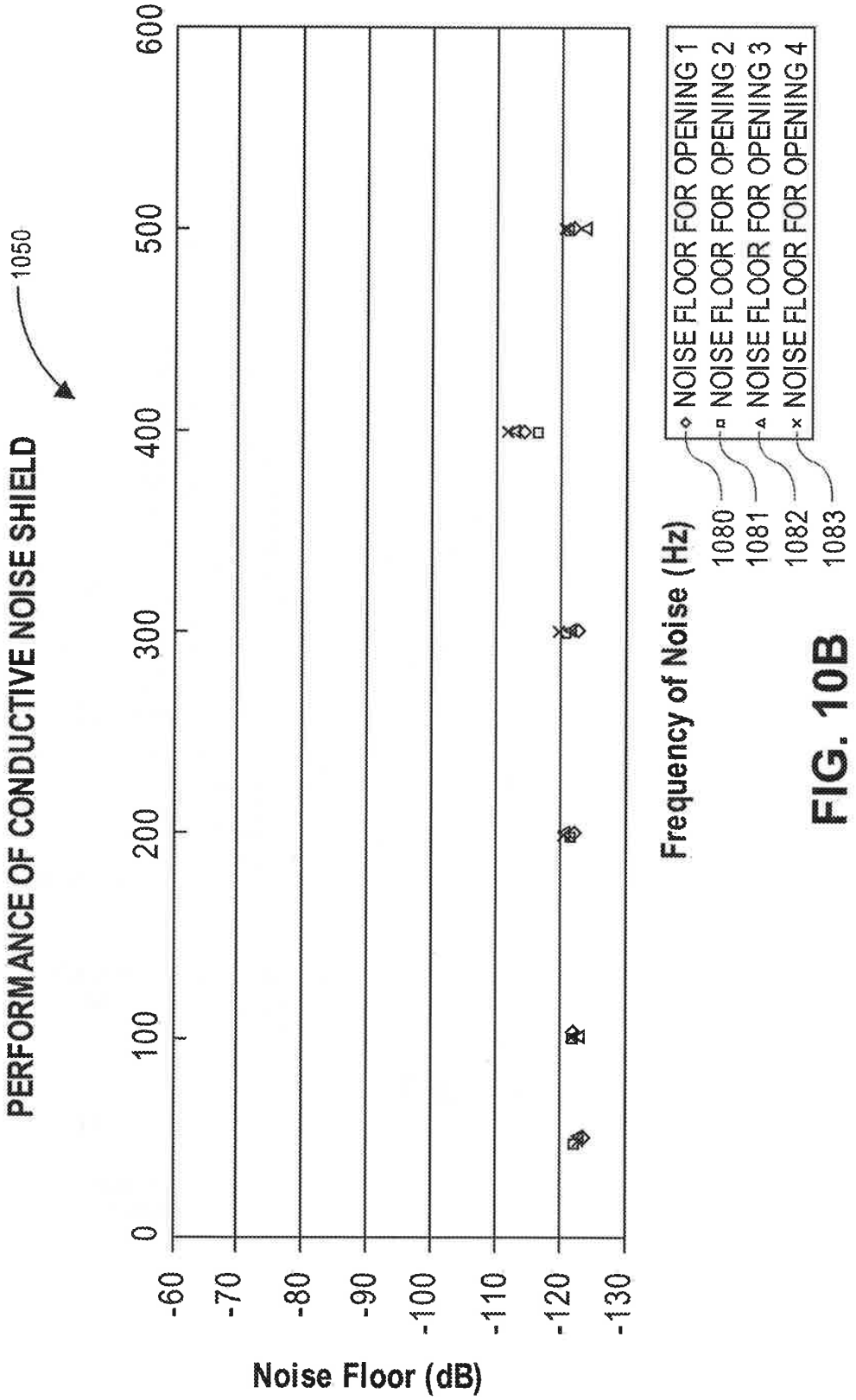


FIG. 10B

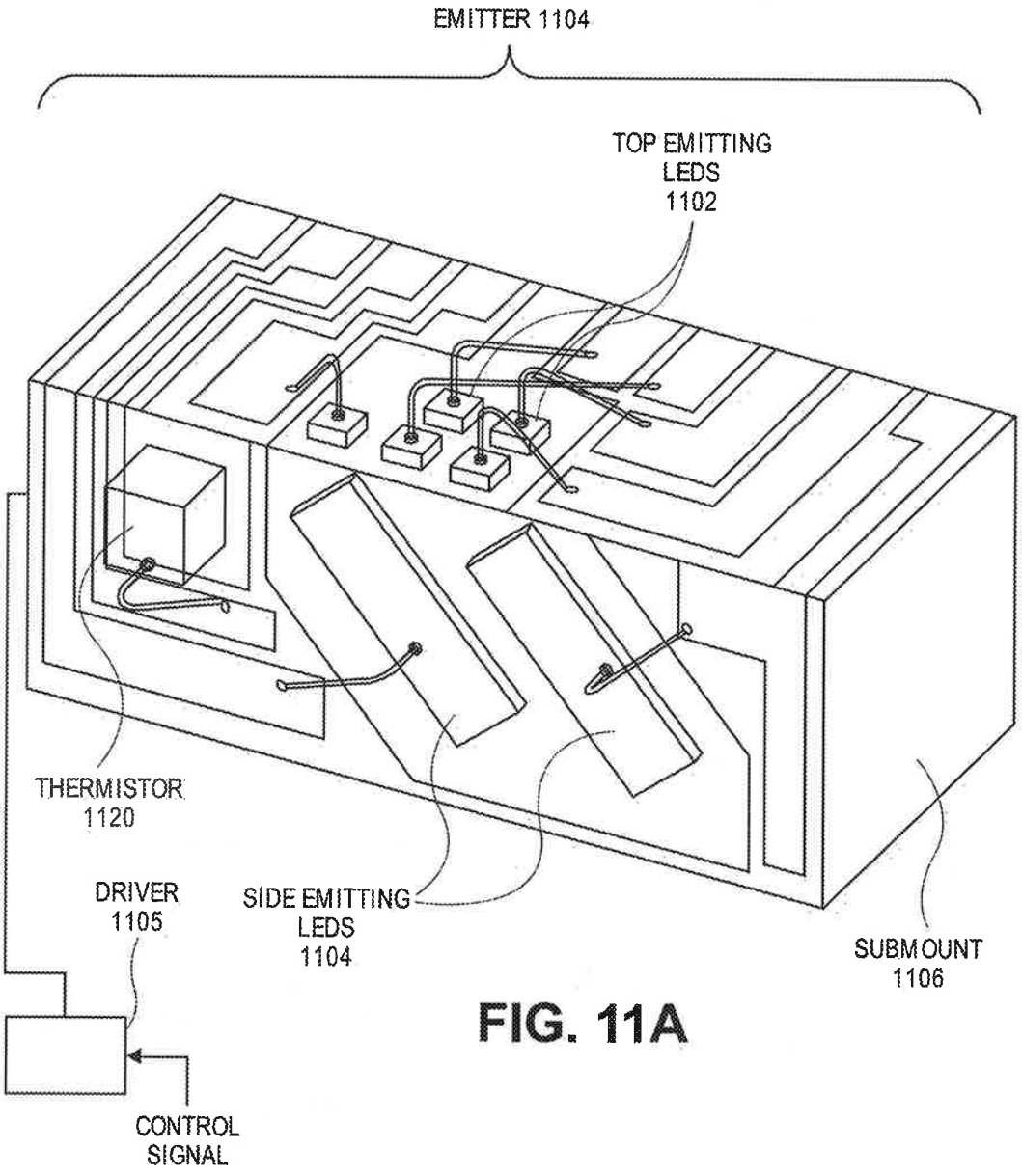


FIG. 11A

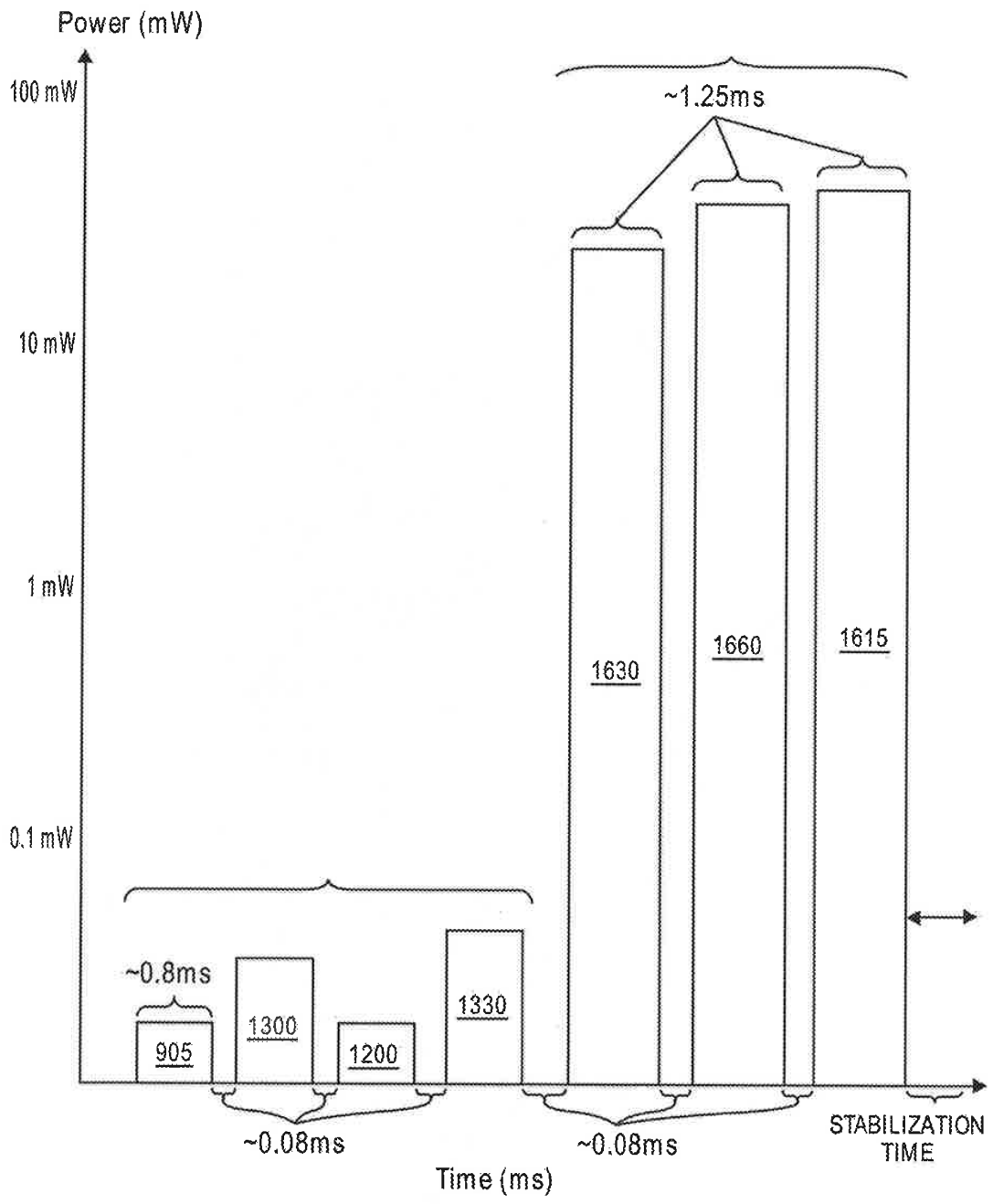


FIG. 11B

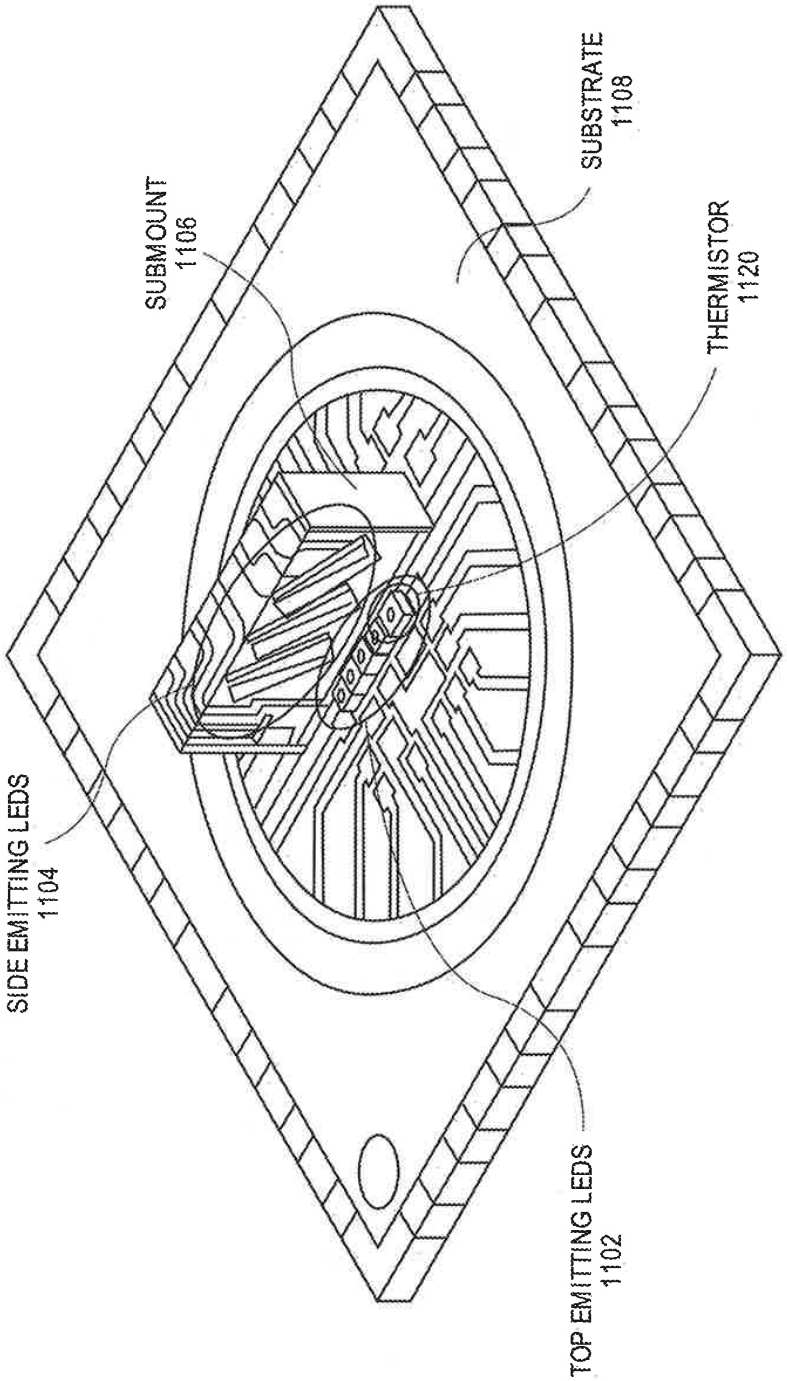


FIG. 11C

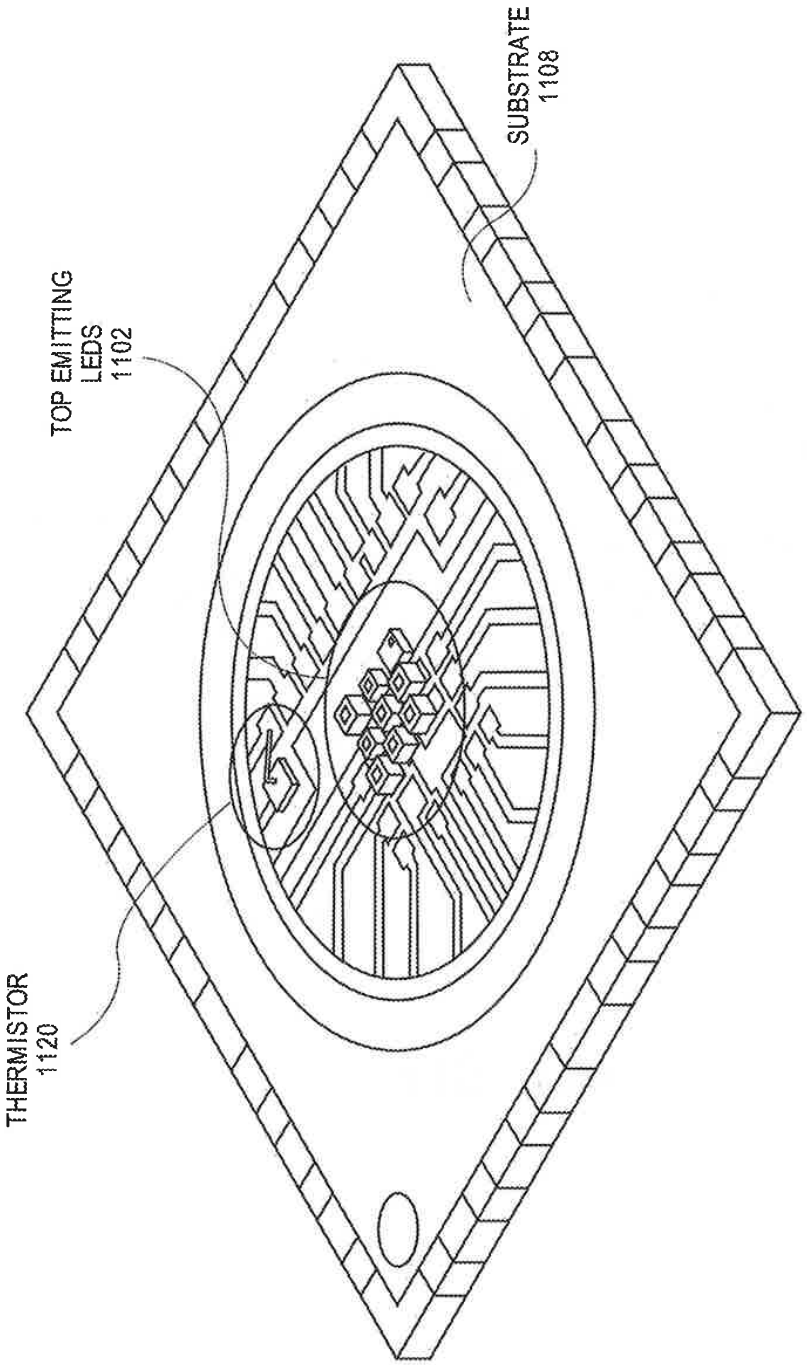


FIG. 11D

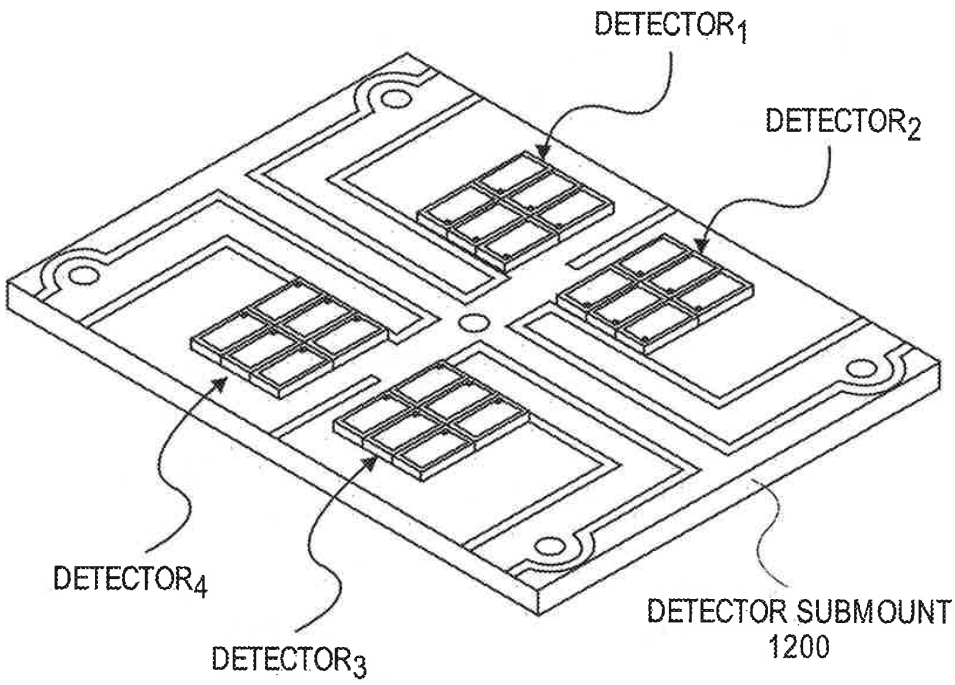
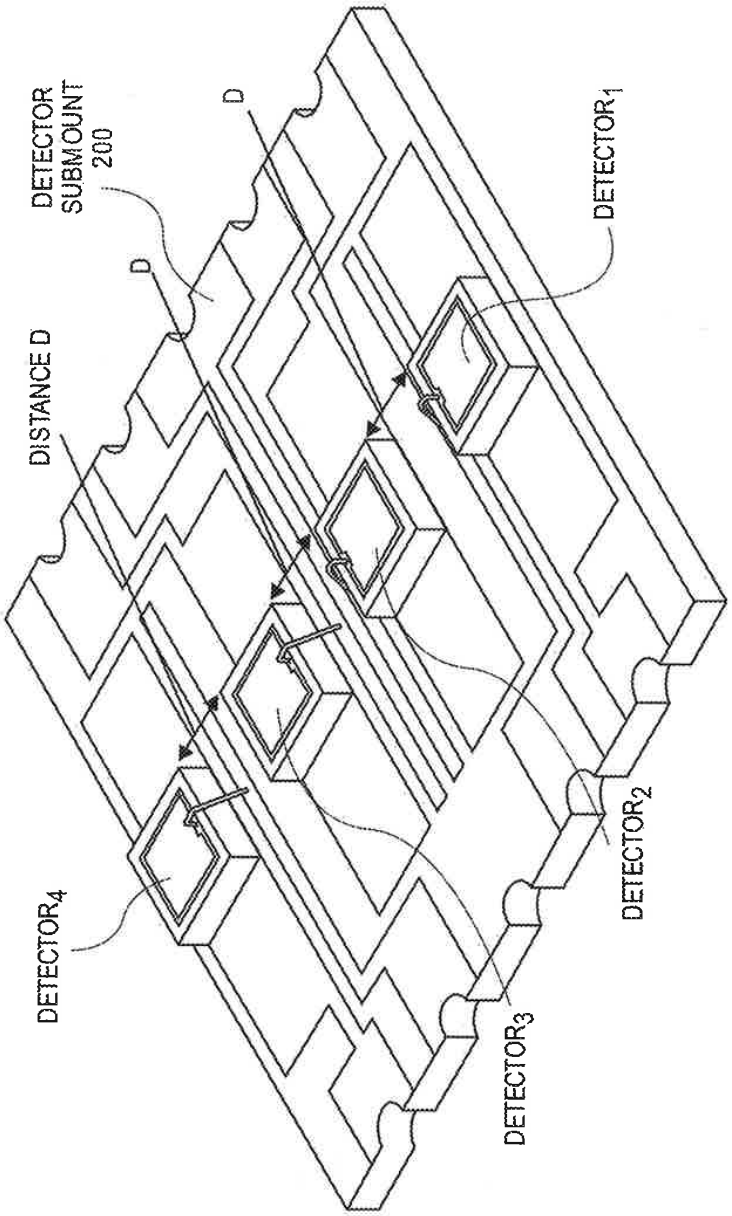


FIG. 12A



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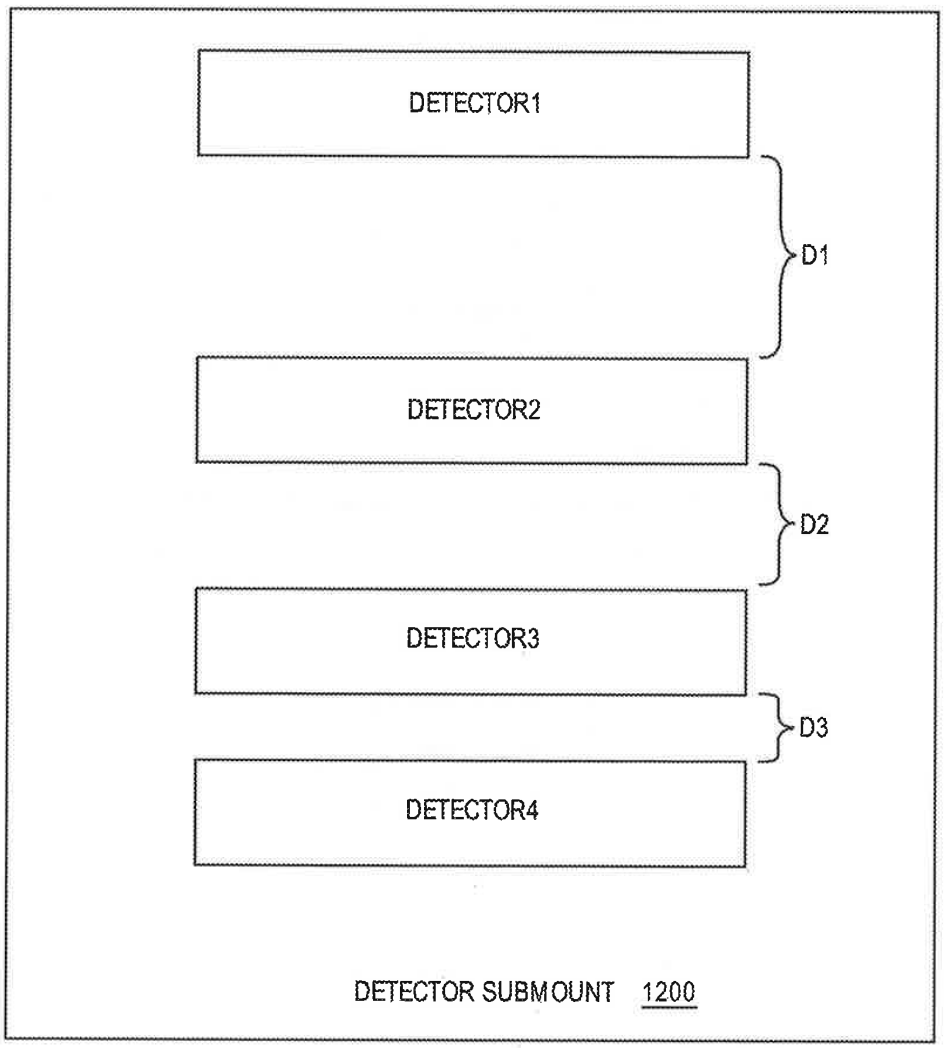

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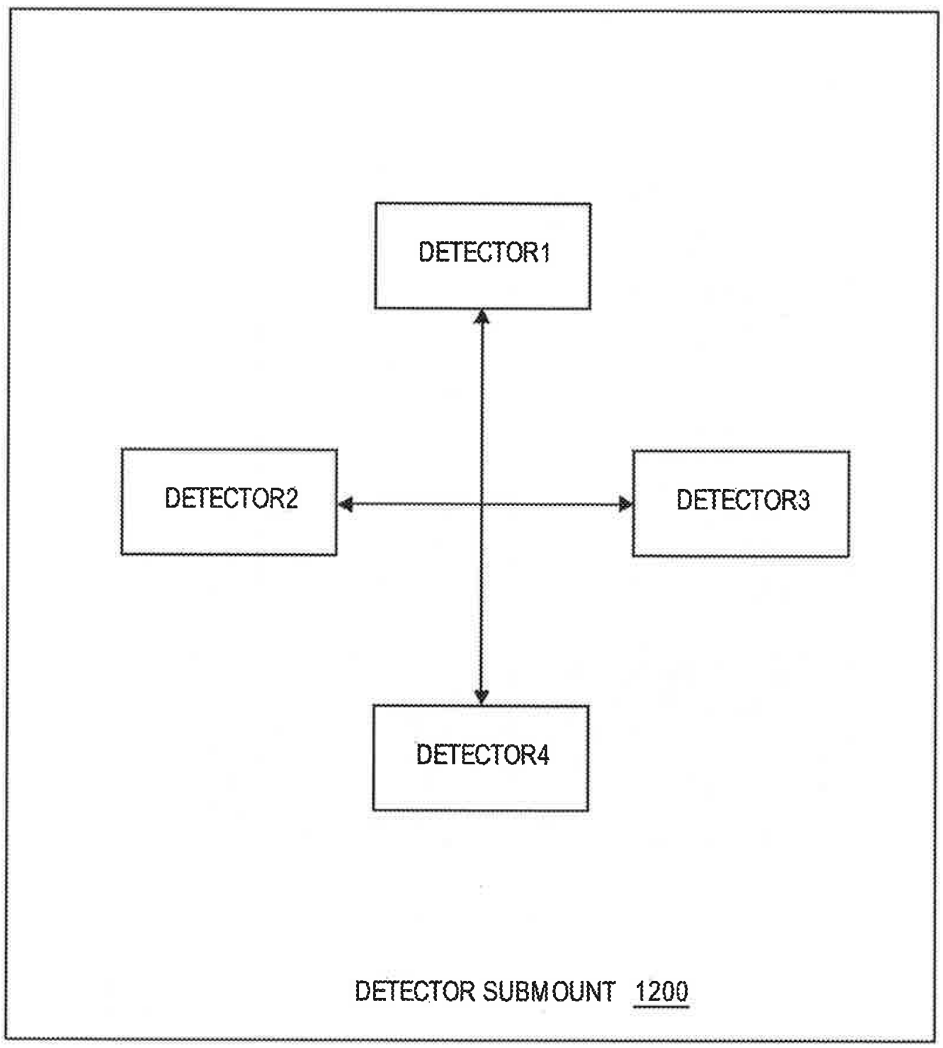

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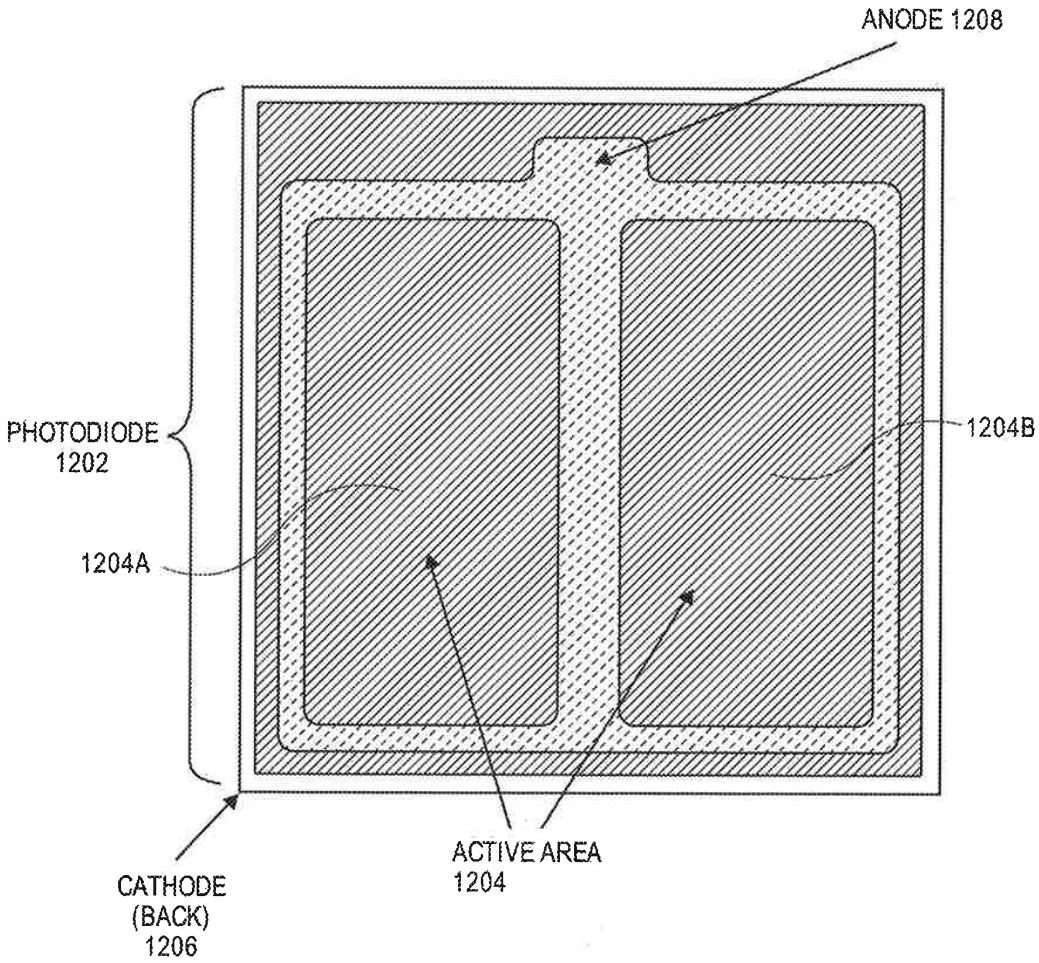
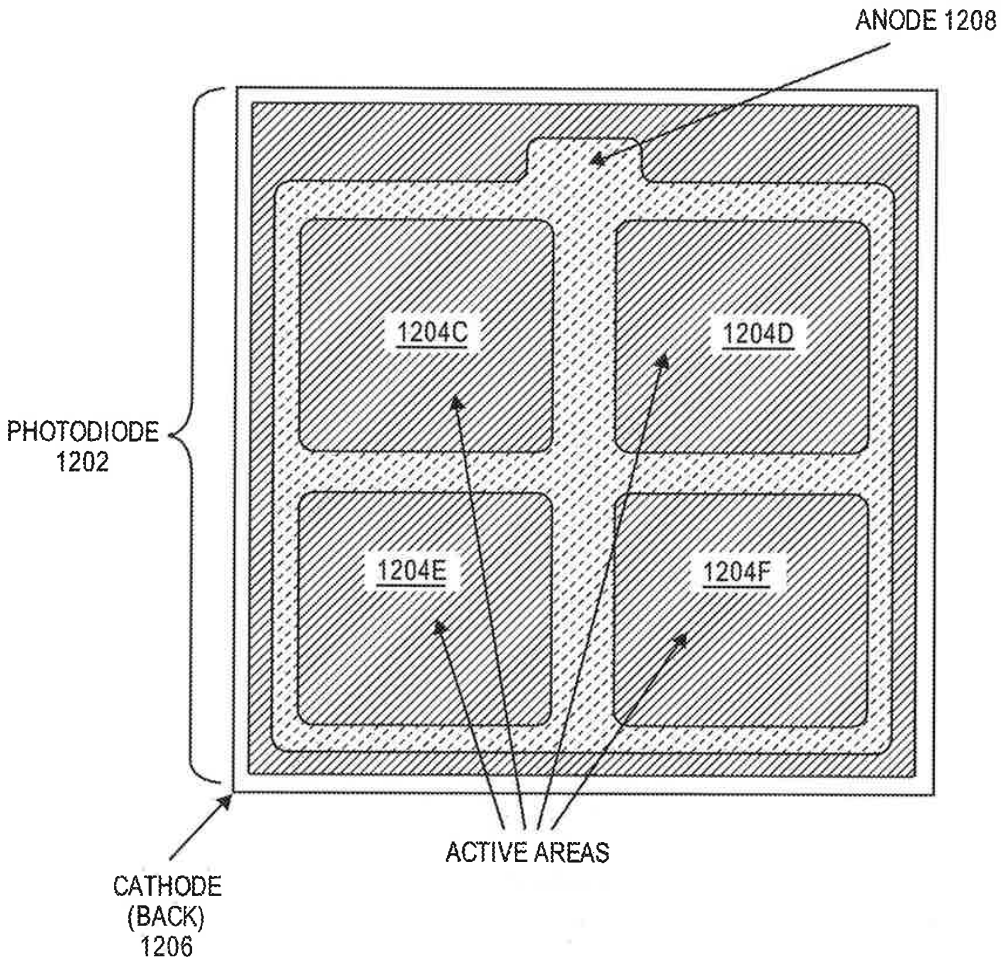


FIG. 12E



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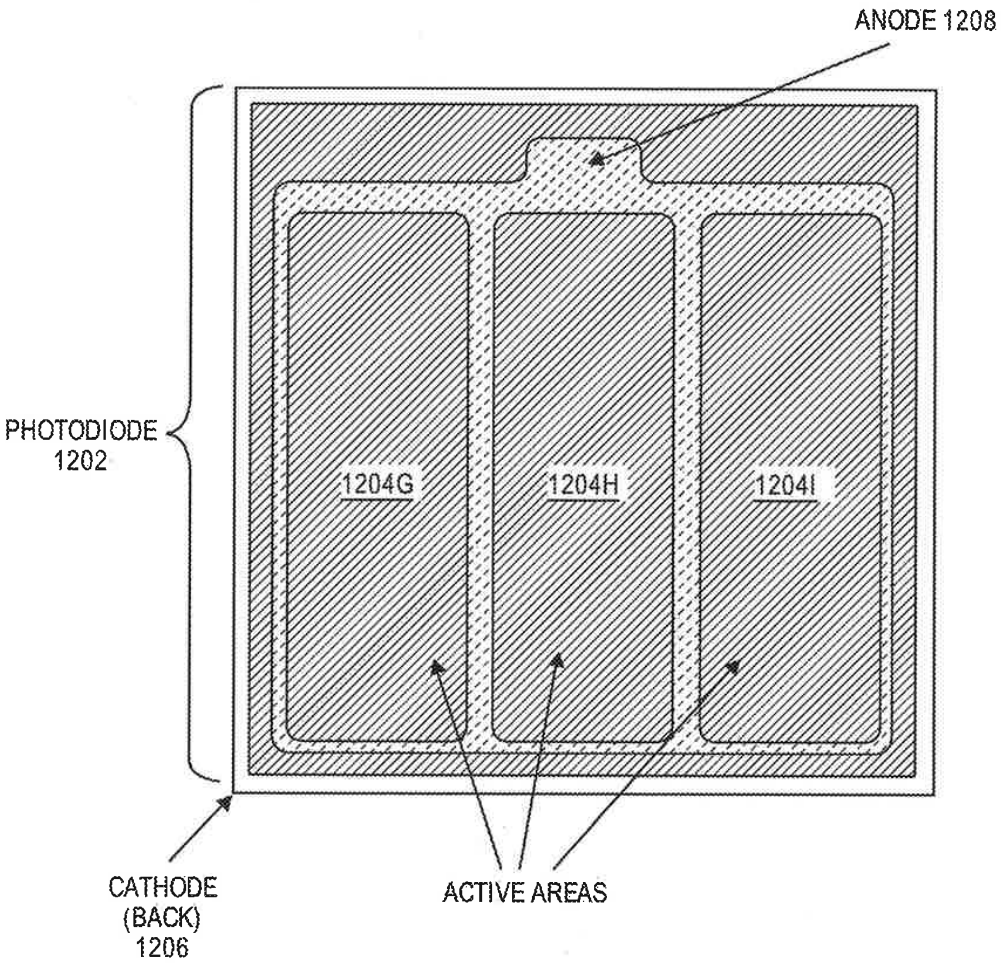


FIG. 12G

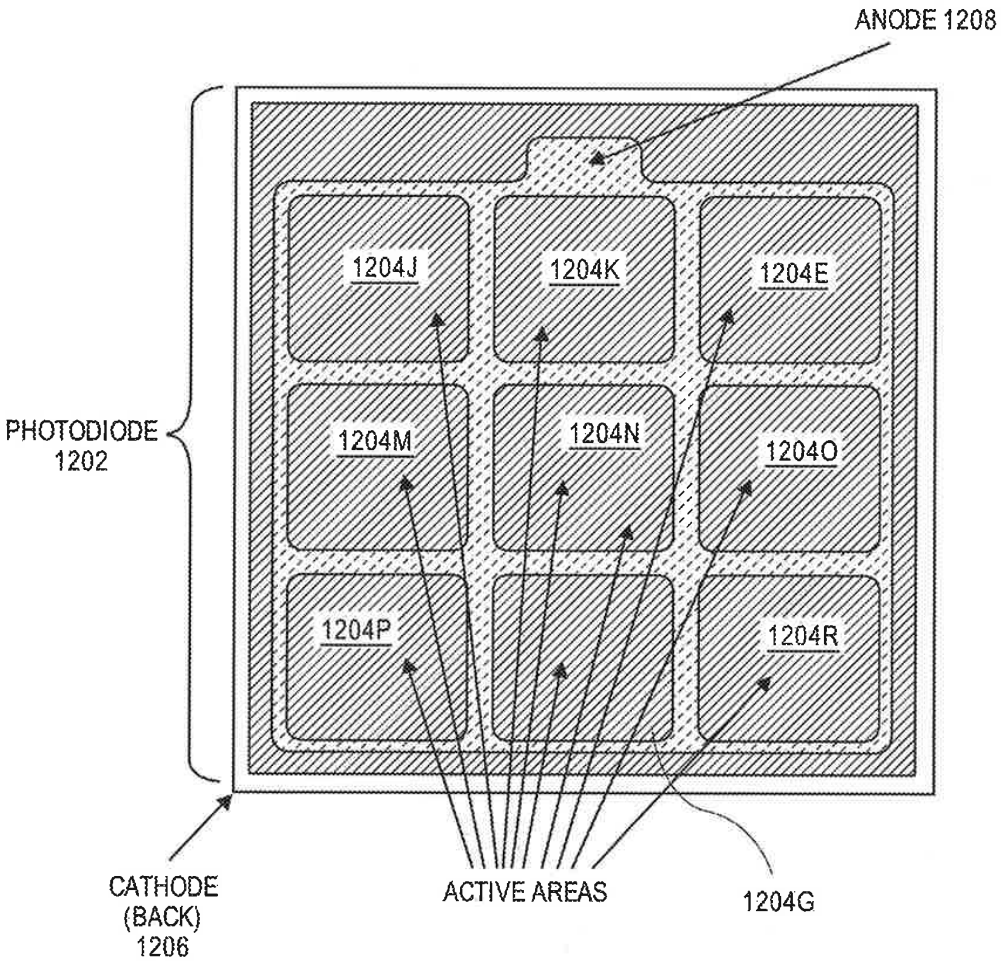
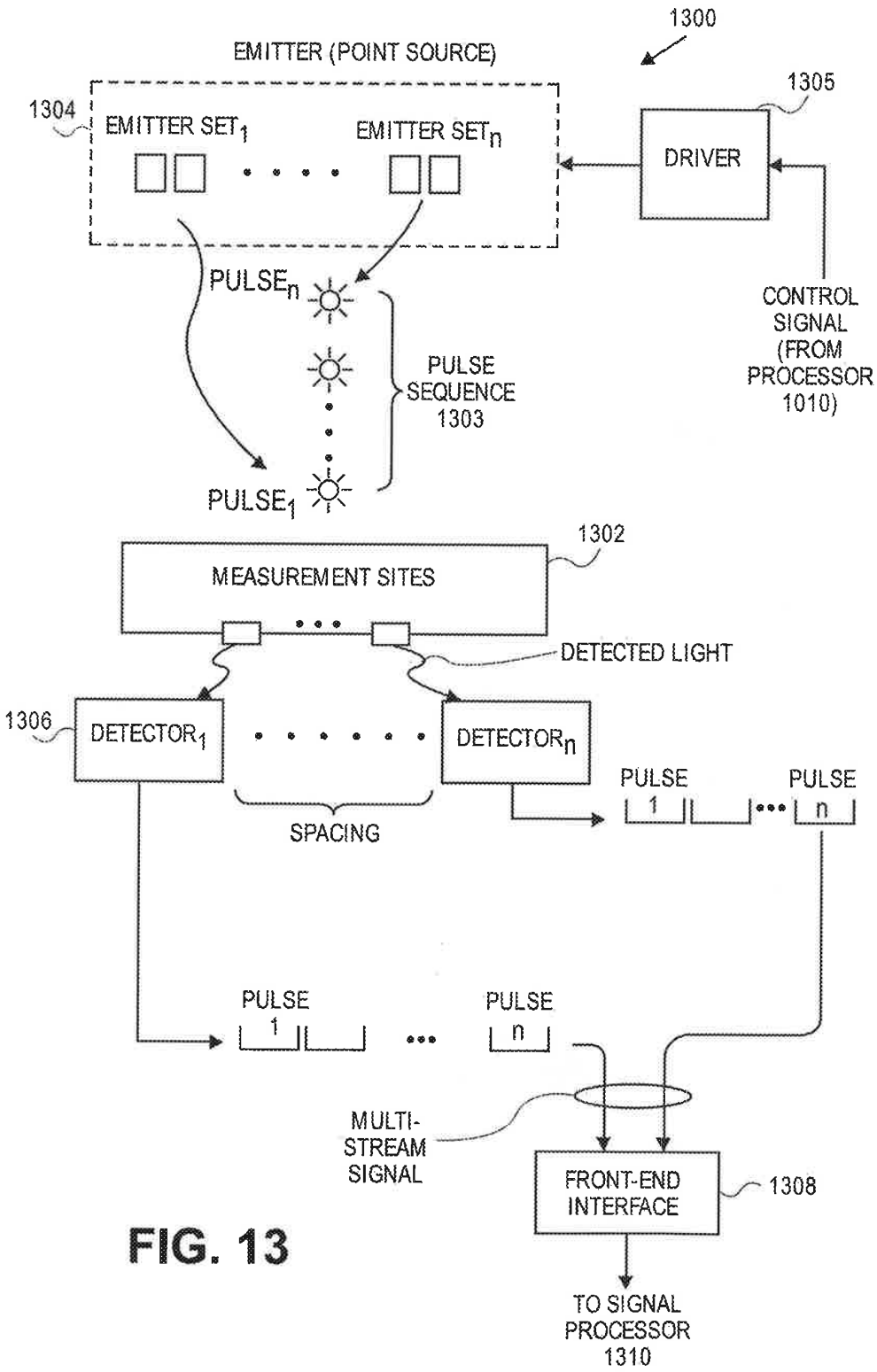


FIG. 12H



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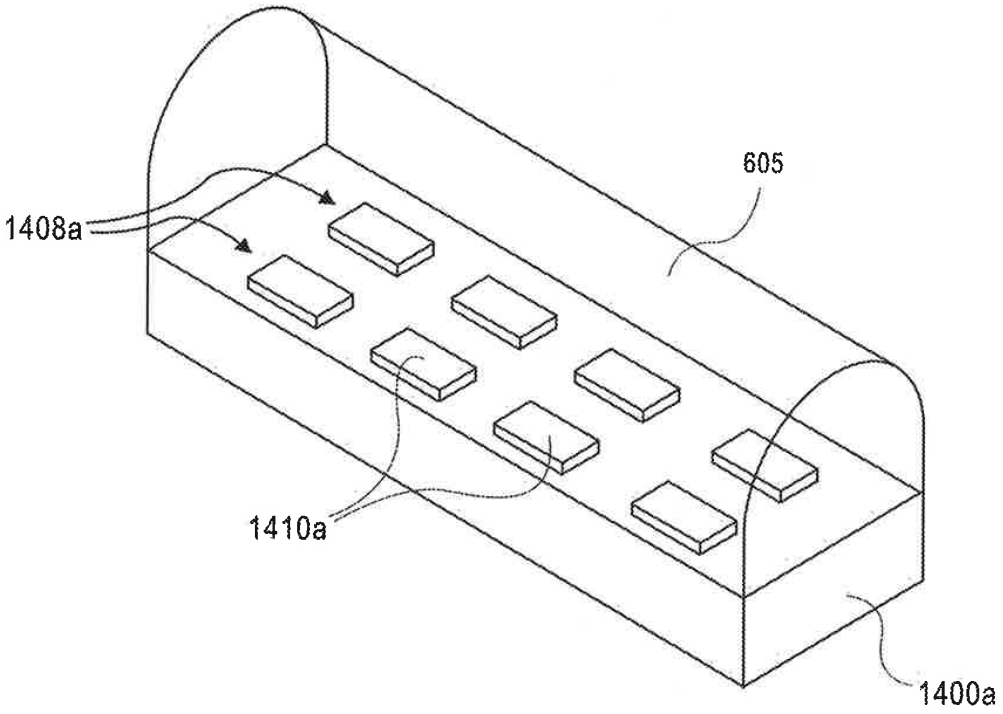
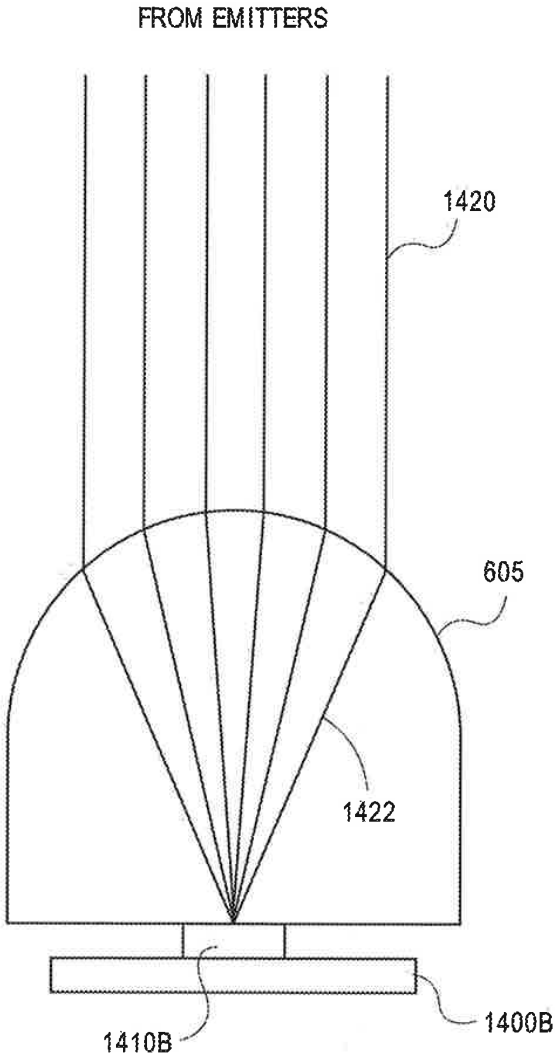


FIG. 14A



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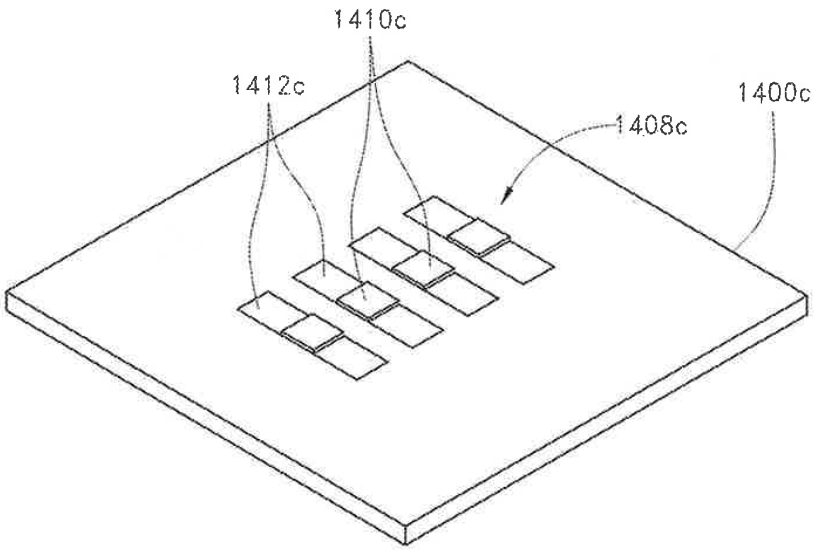

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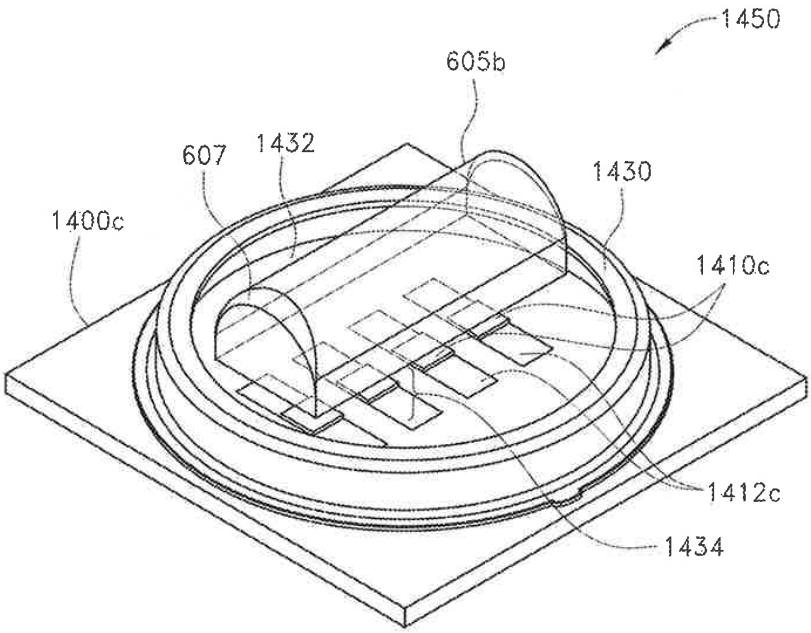

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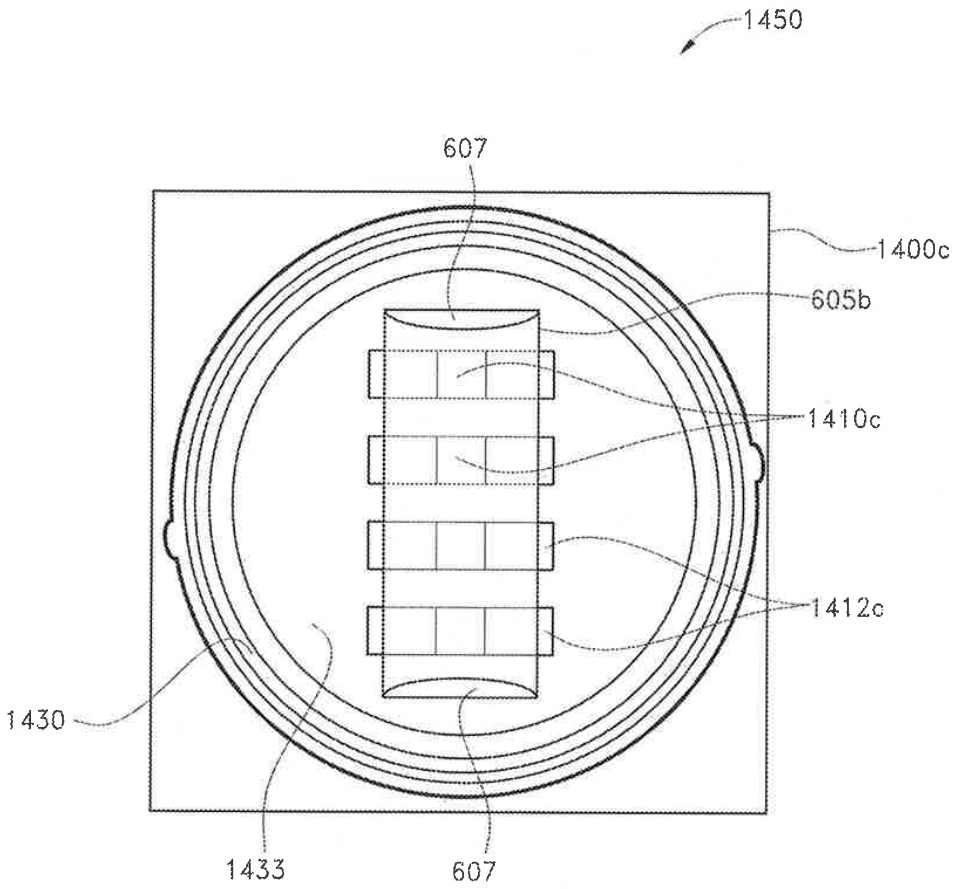

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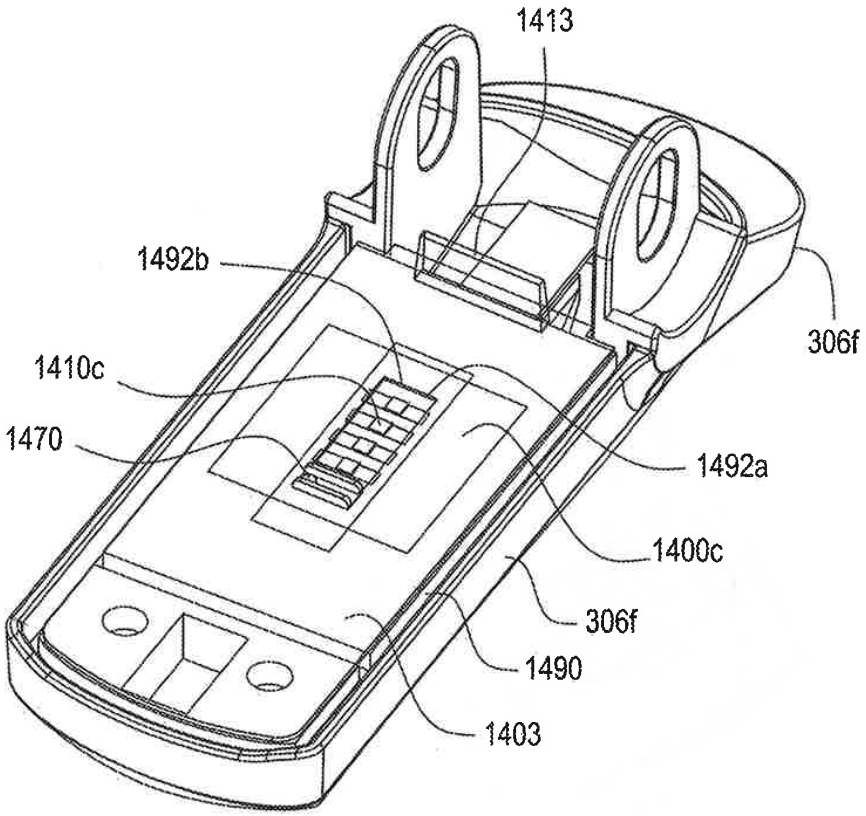

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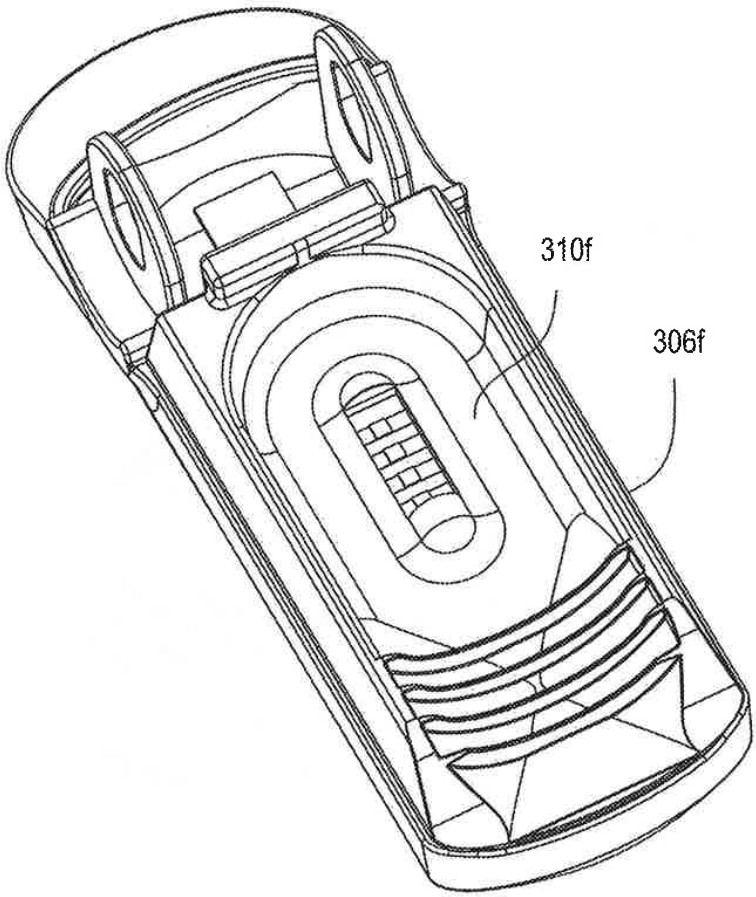

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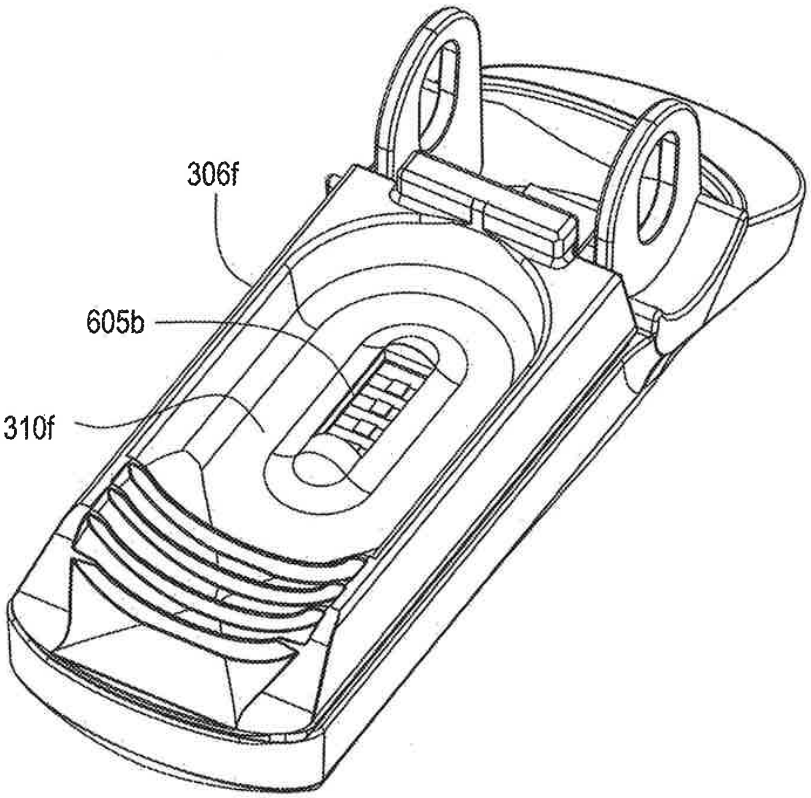


FIG. 14H

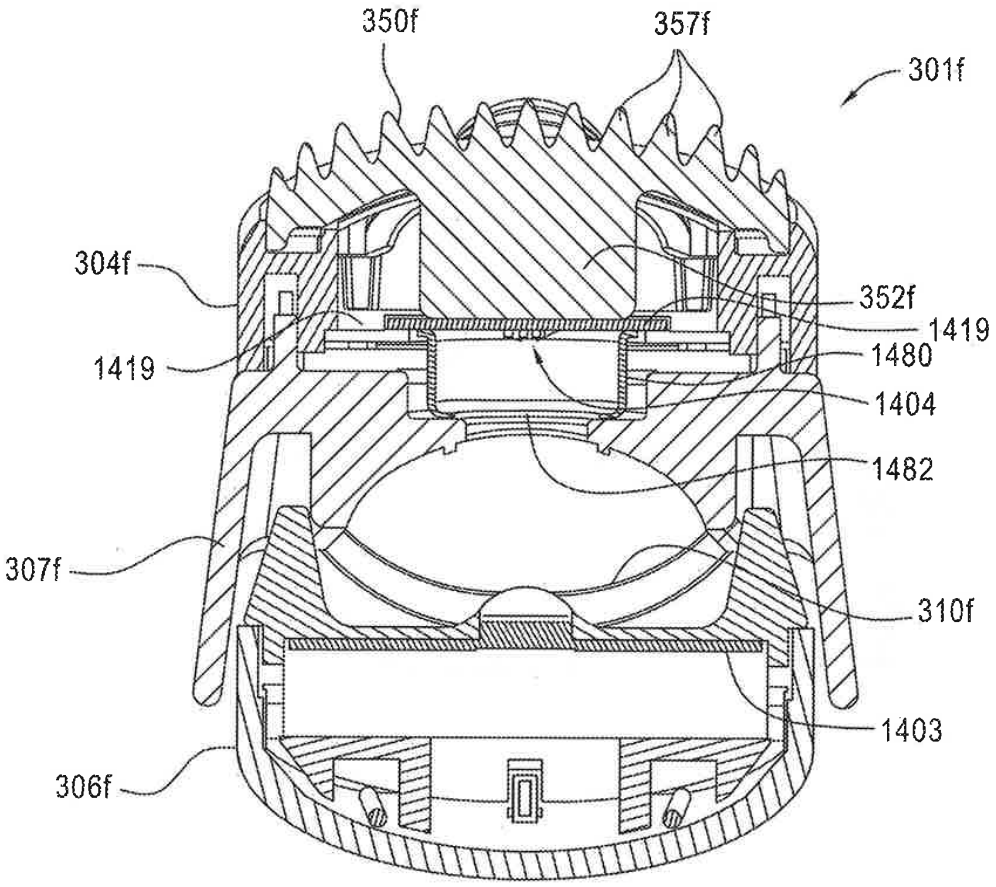


FIG. 14I

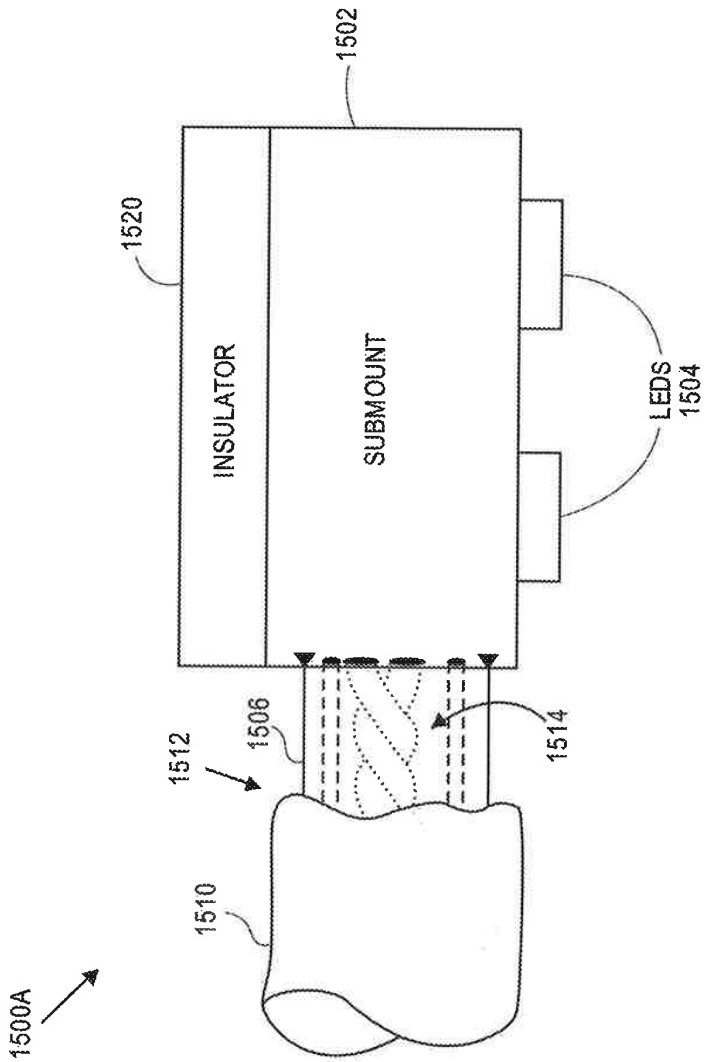


FIG. 15A

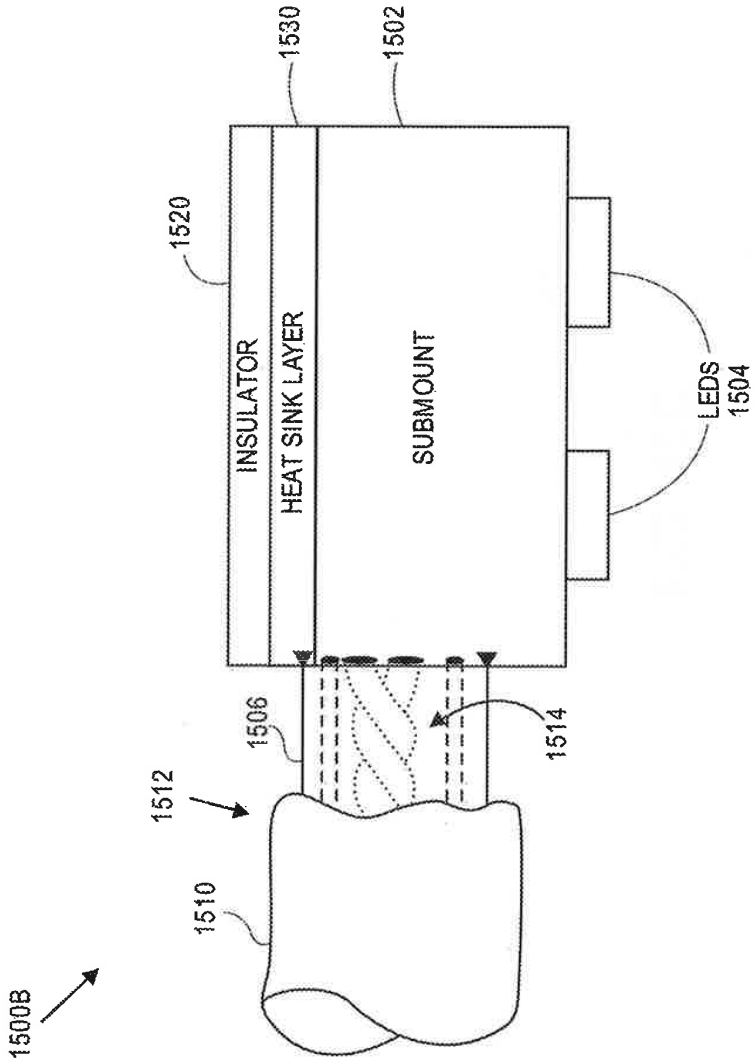


FIG. 15B

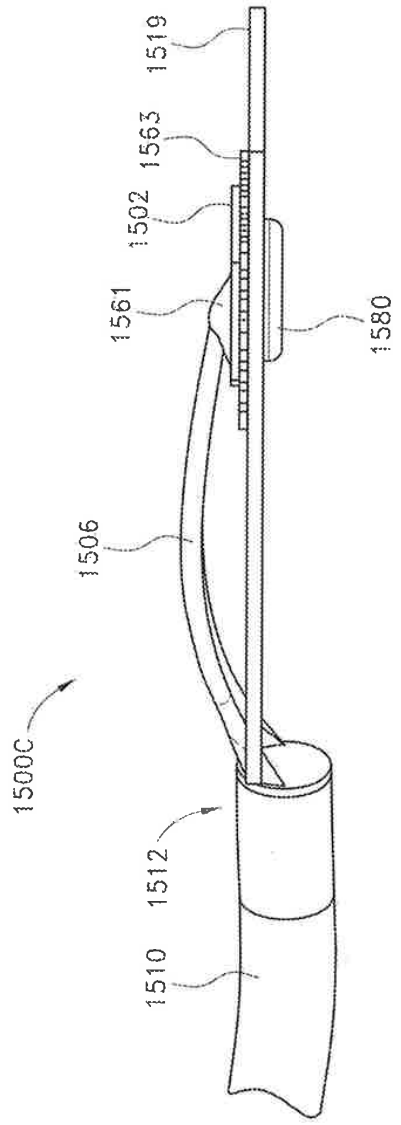


FIG. 15C

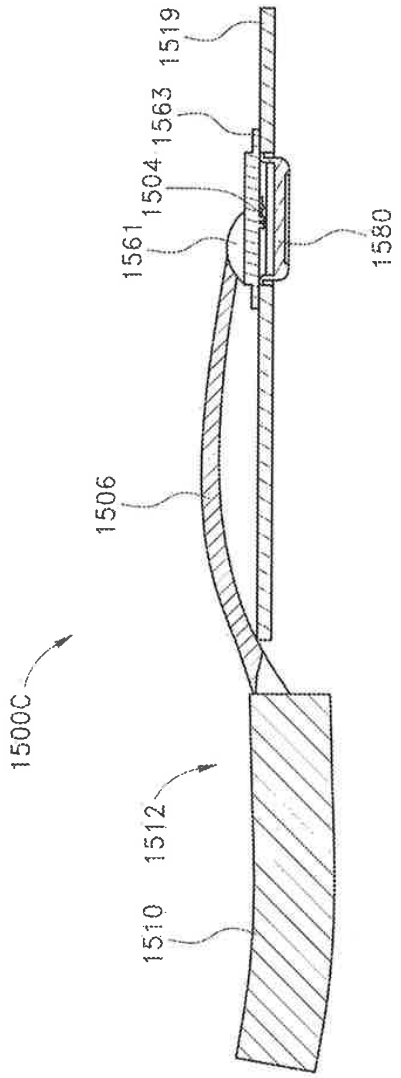


FIG. 15D

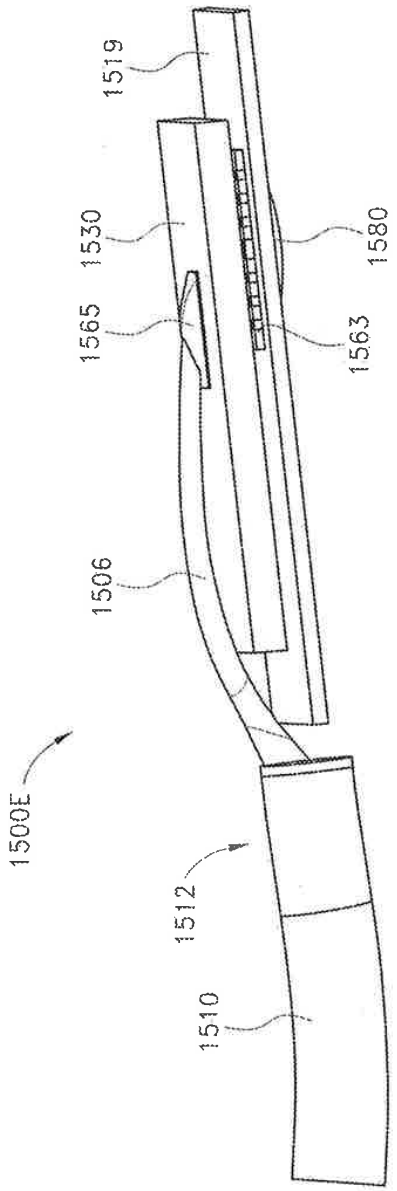


FIG. 15E

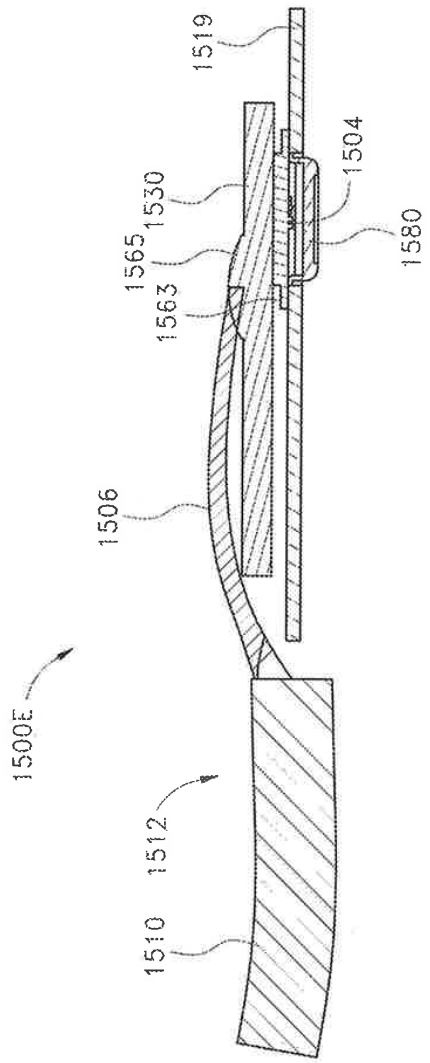


FIG. 15F

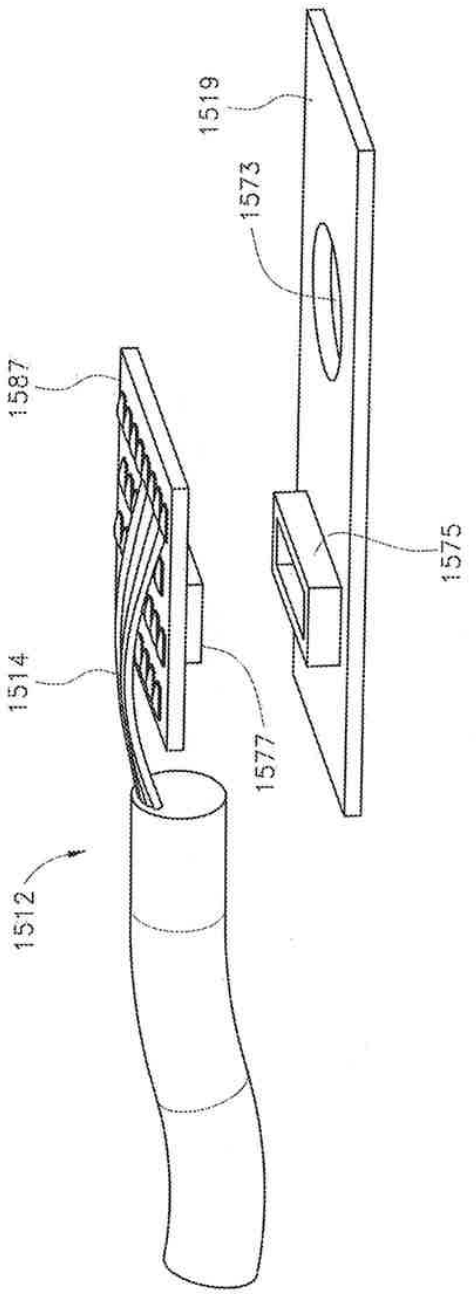


FIG. 15G

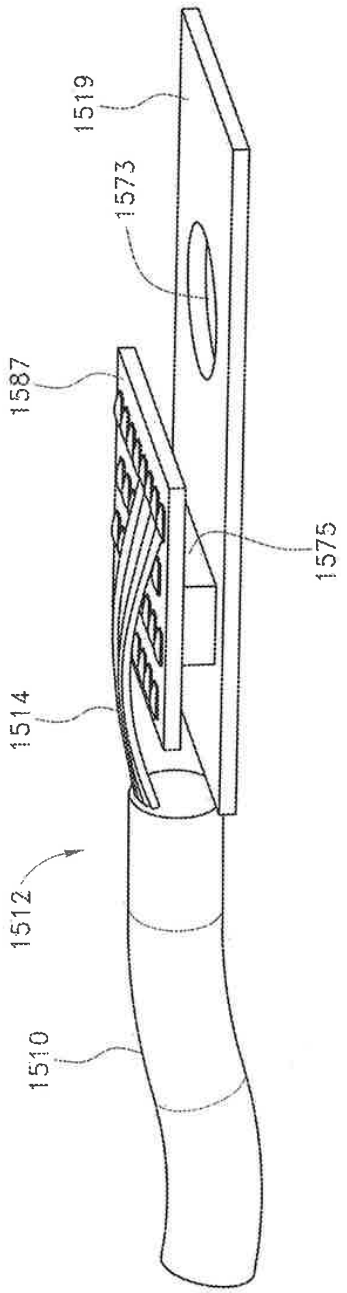


FIG. 15H

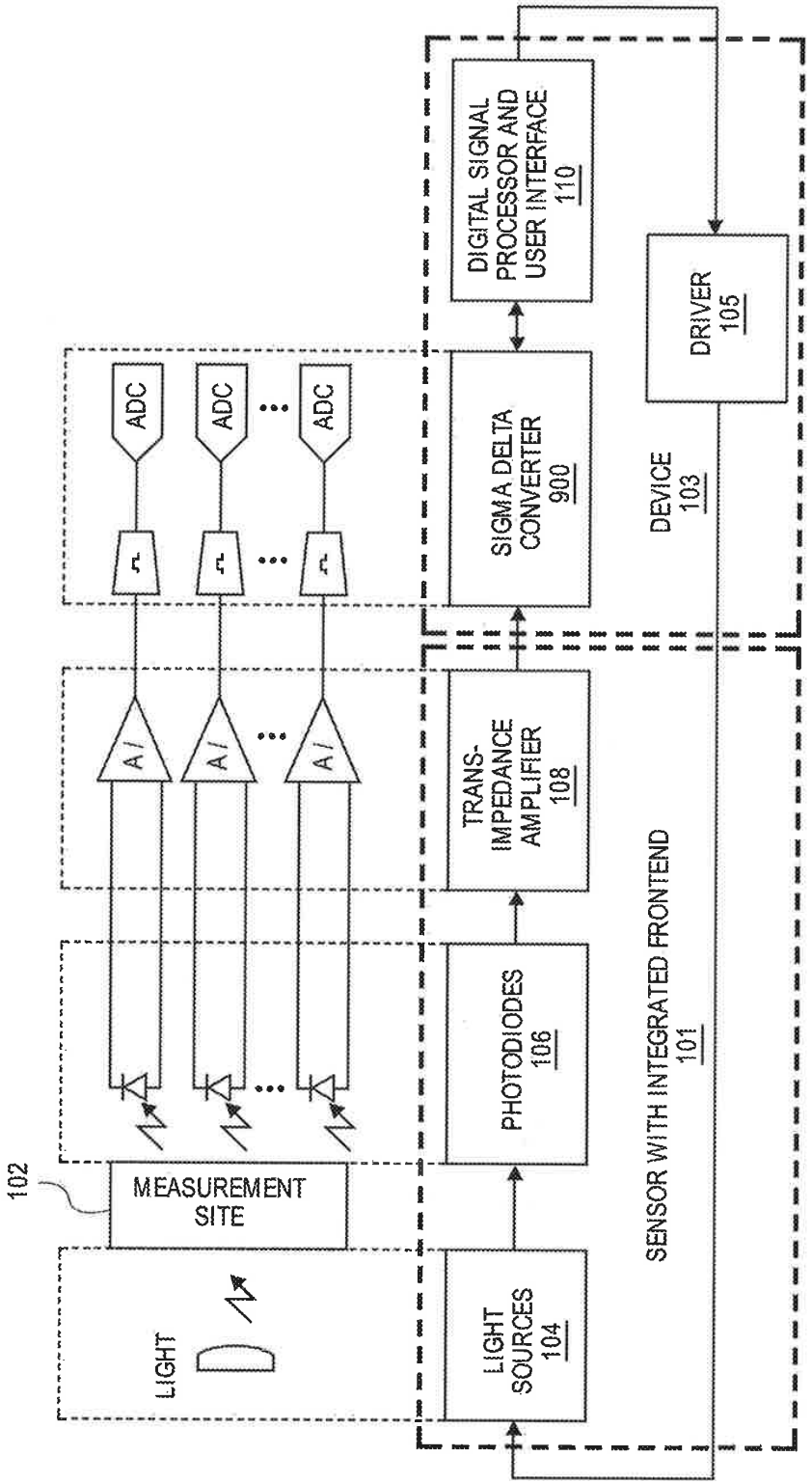


FIG. 15I

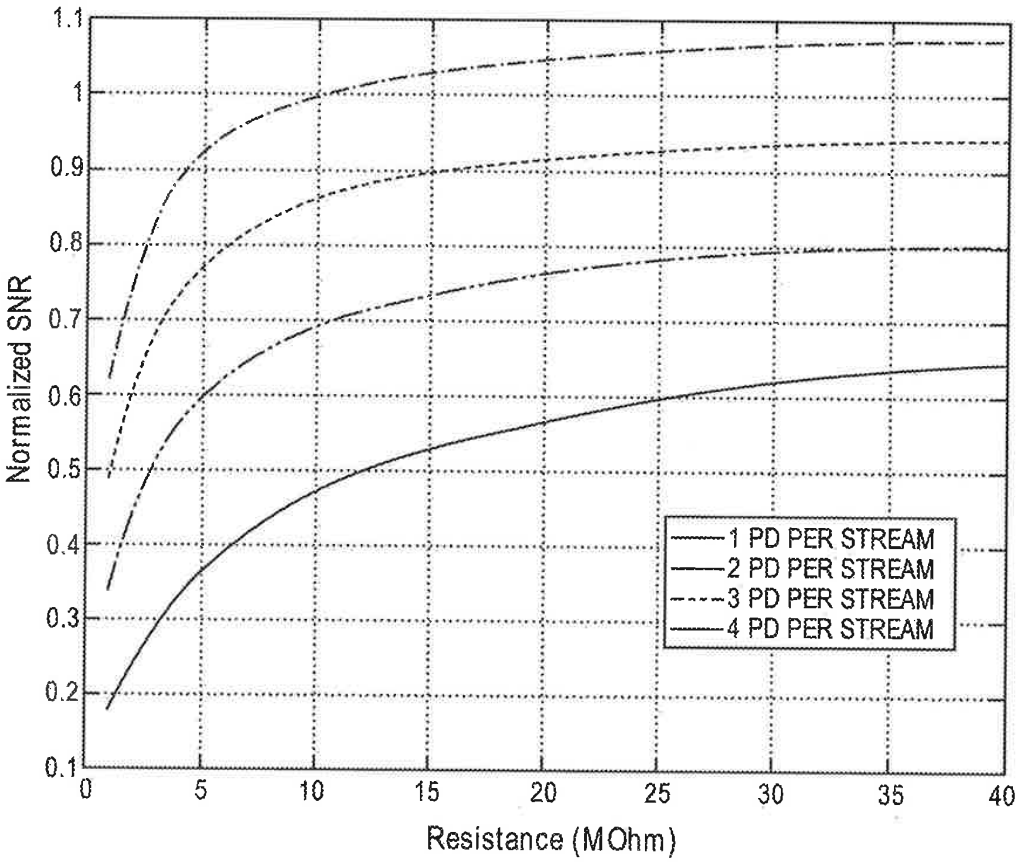


FIG. 15J

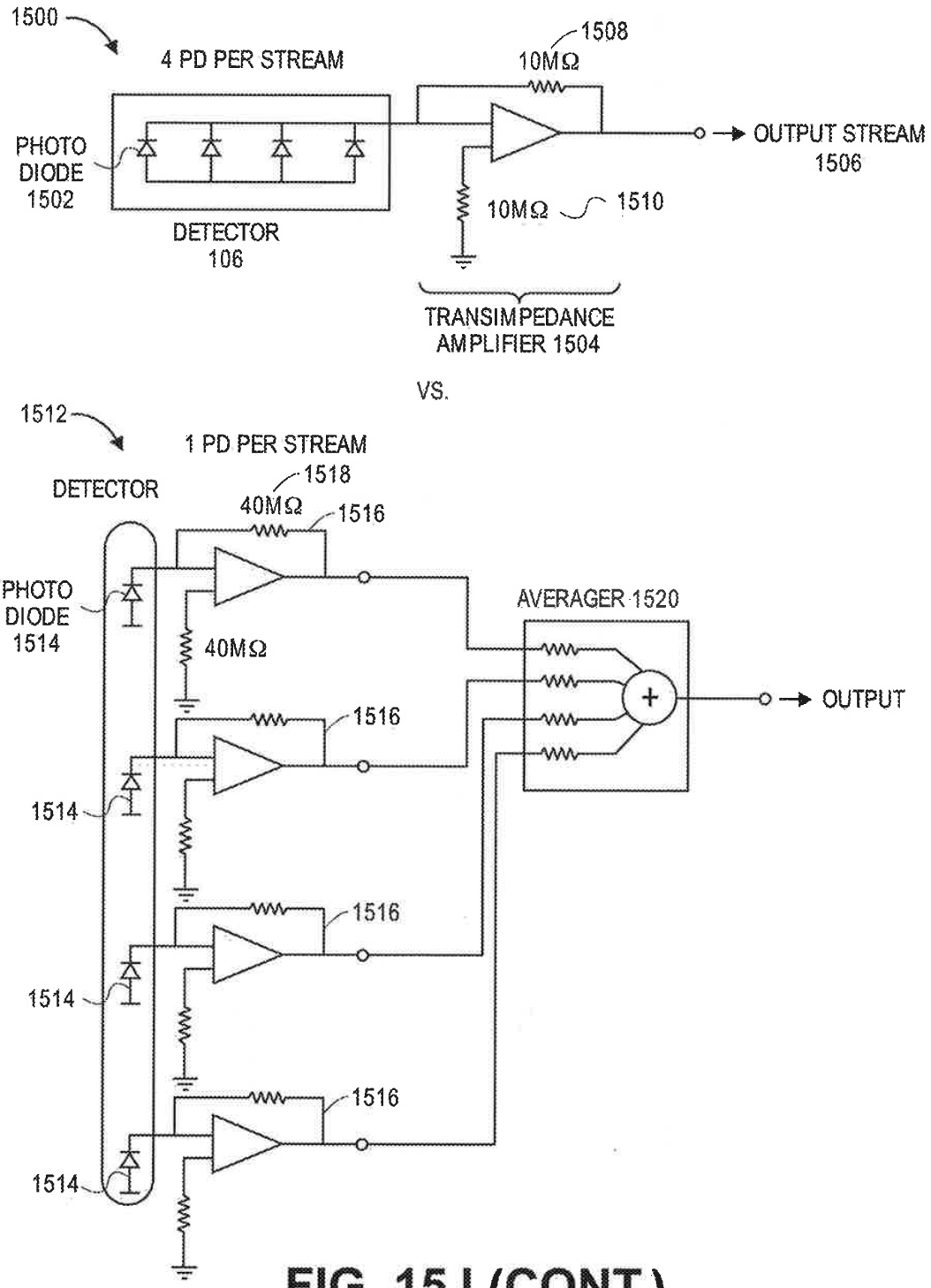
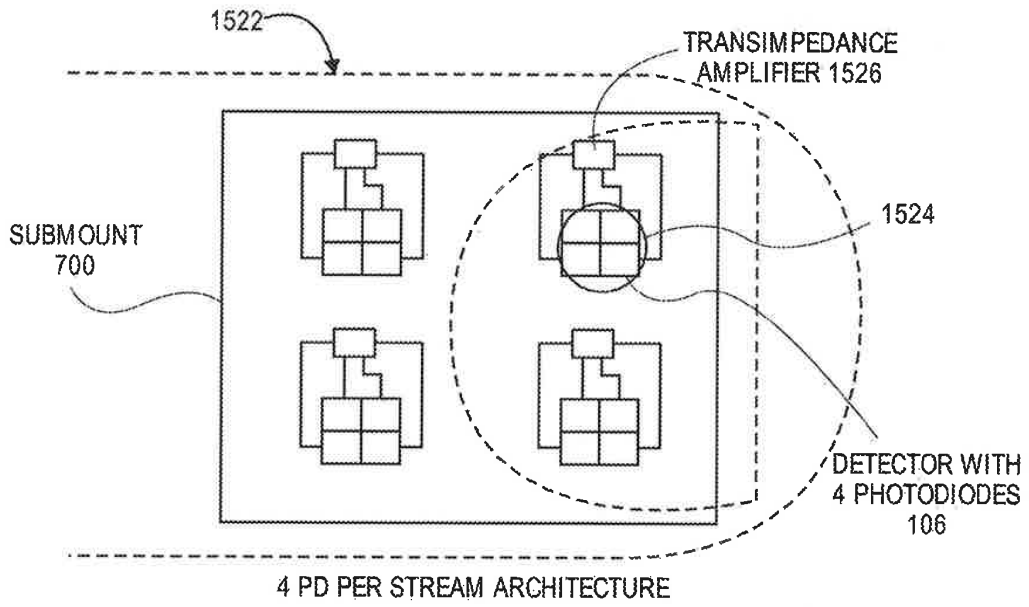


FIG. 15J (CONT.)



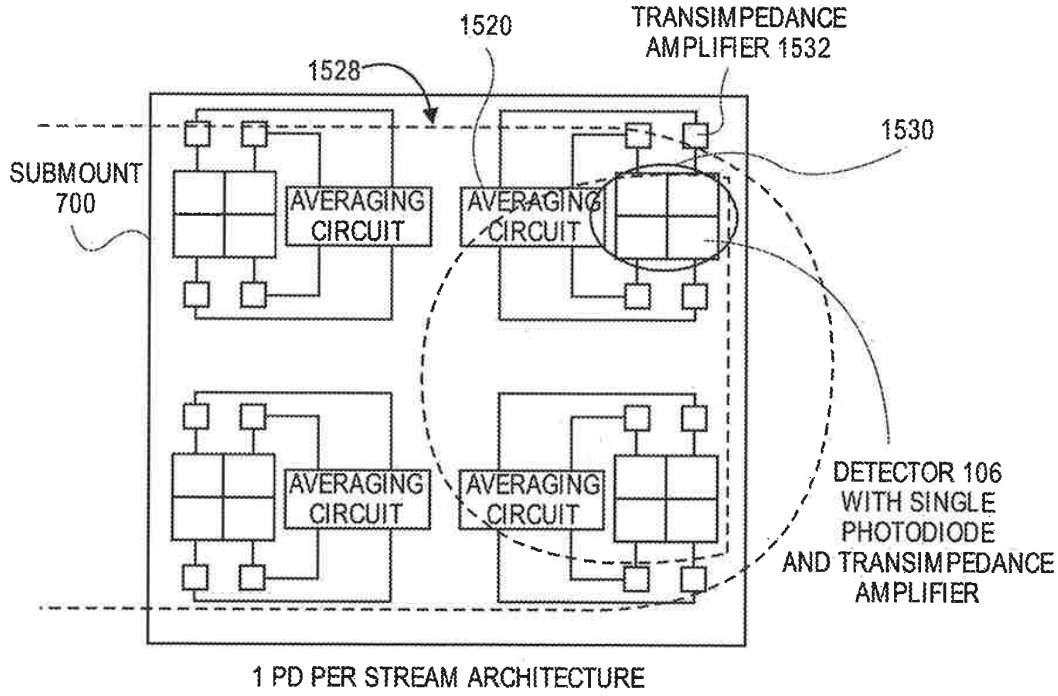


FIG. 15K

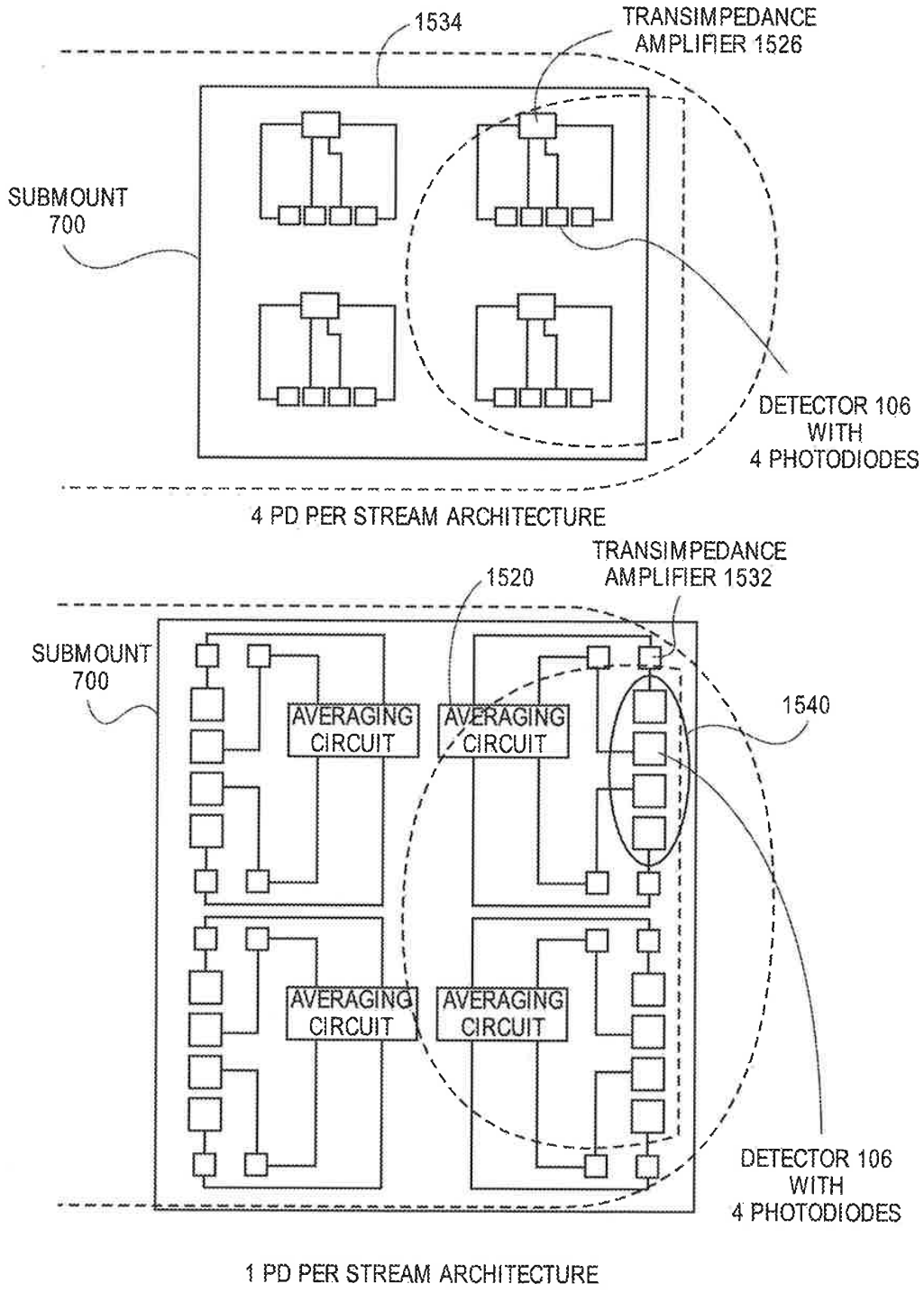


FIG. 15K (CONT.)

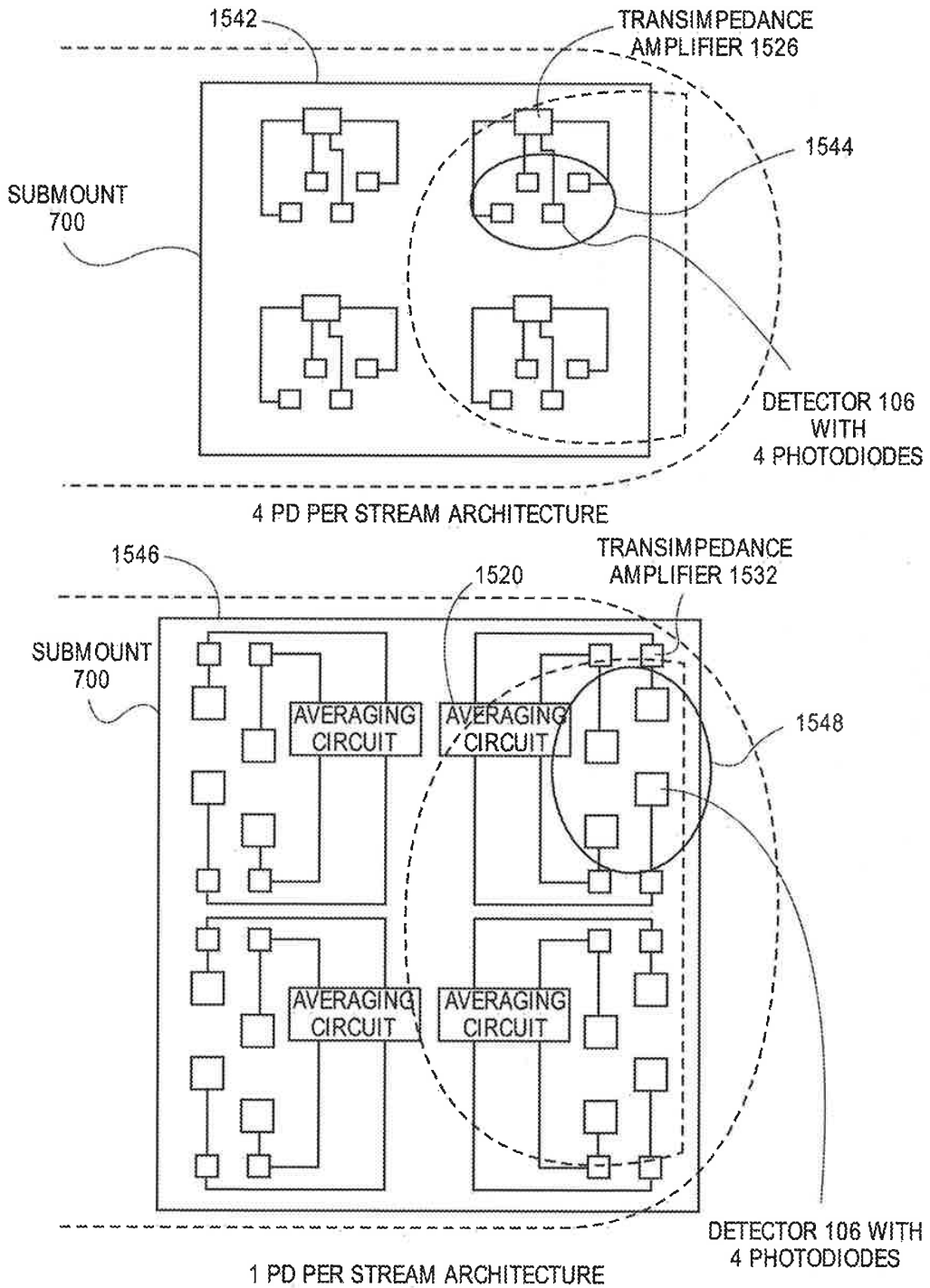


FIG. 15K (CONT.)

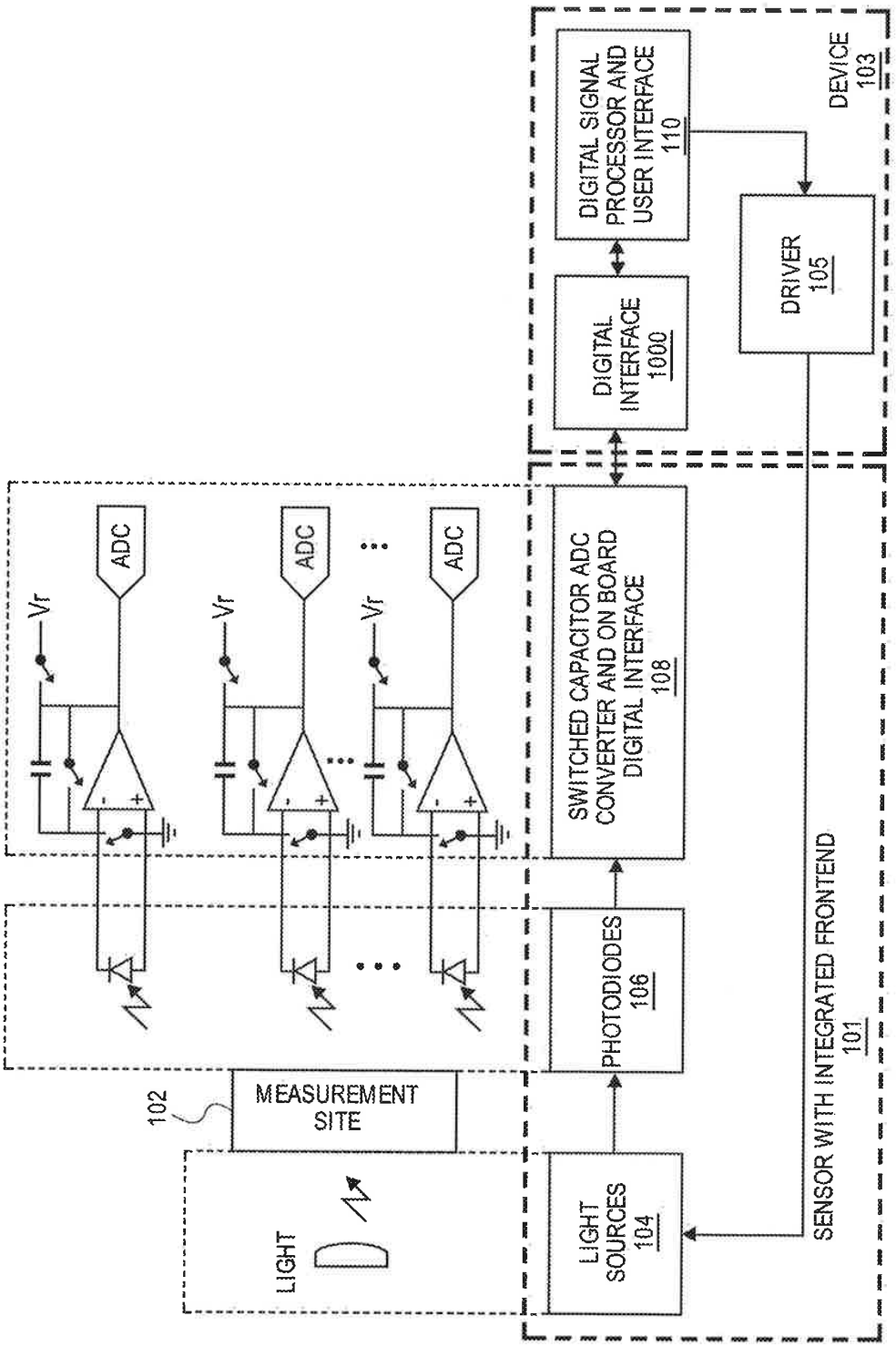


FIG. 15L

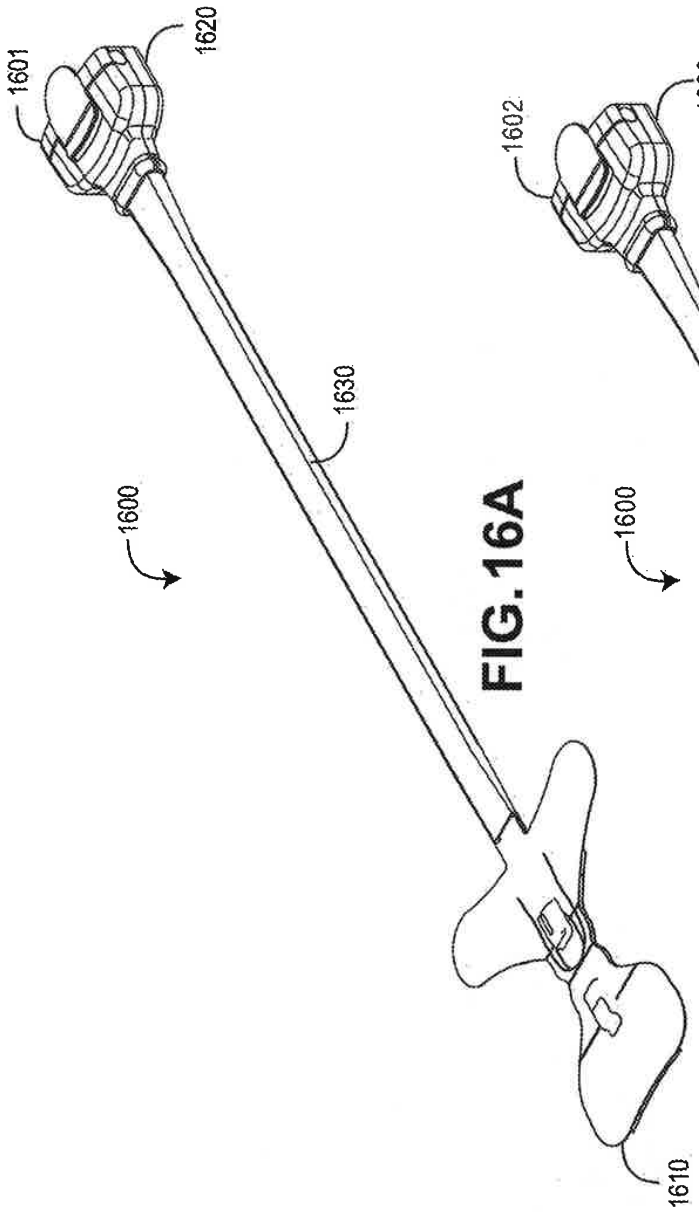


FIG. 16A

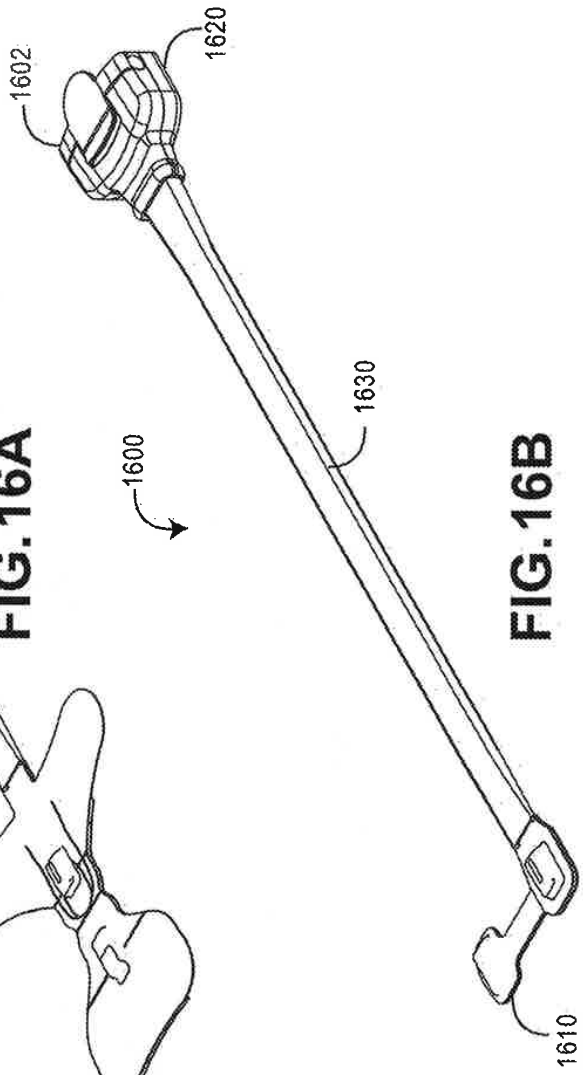


FIG. 16B

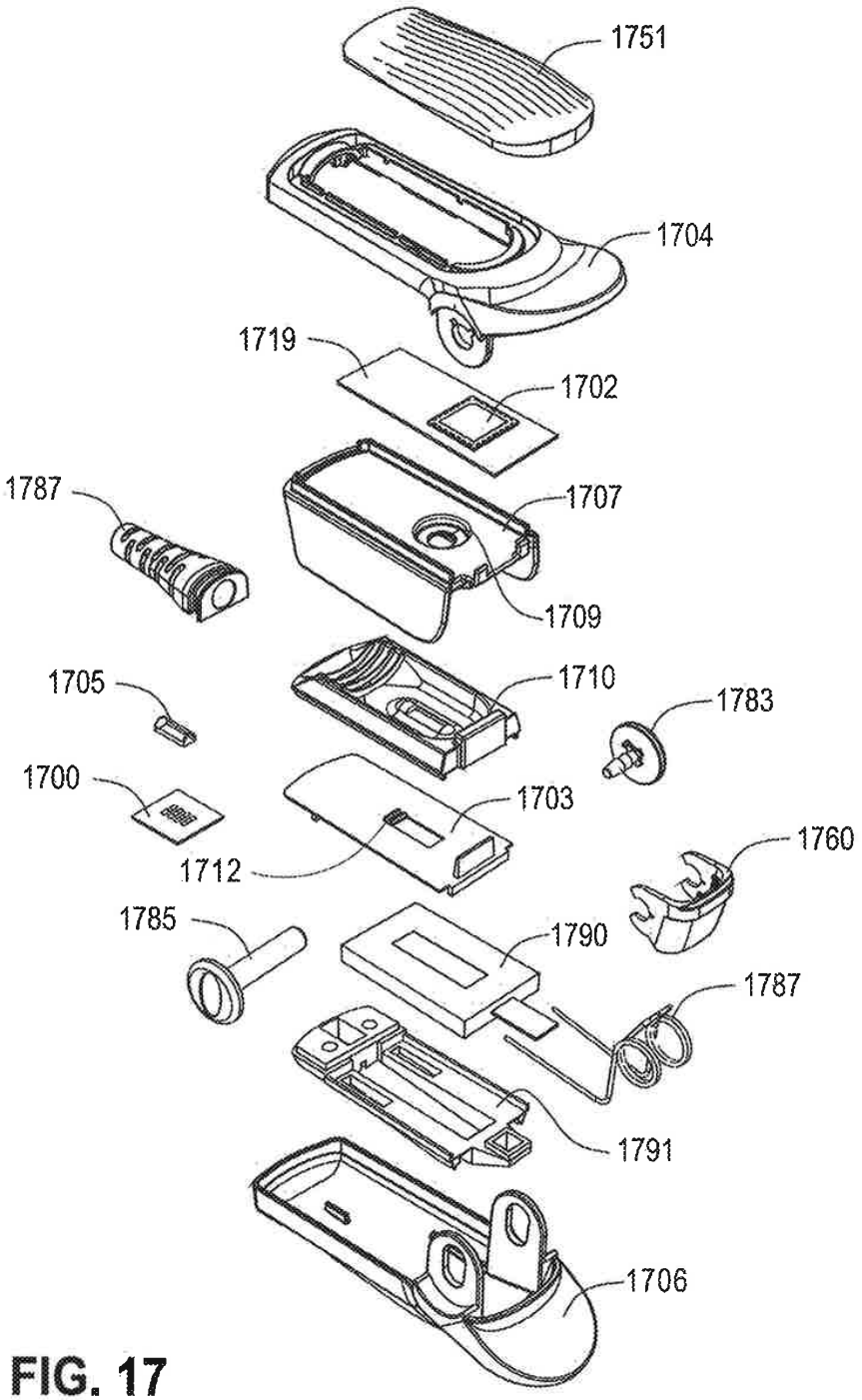


FIG. 17

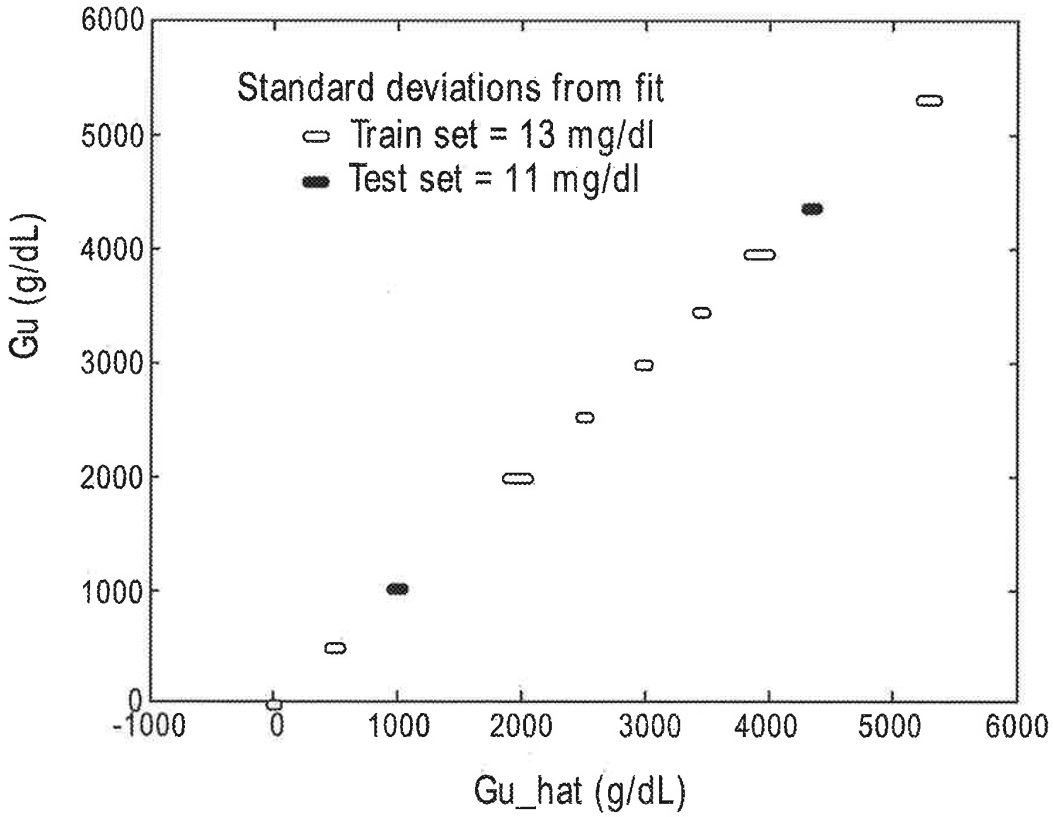


FIG. 18

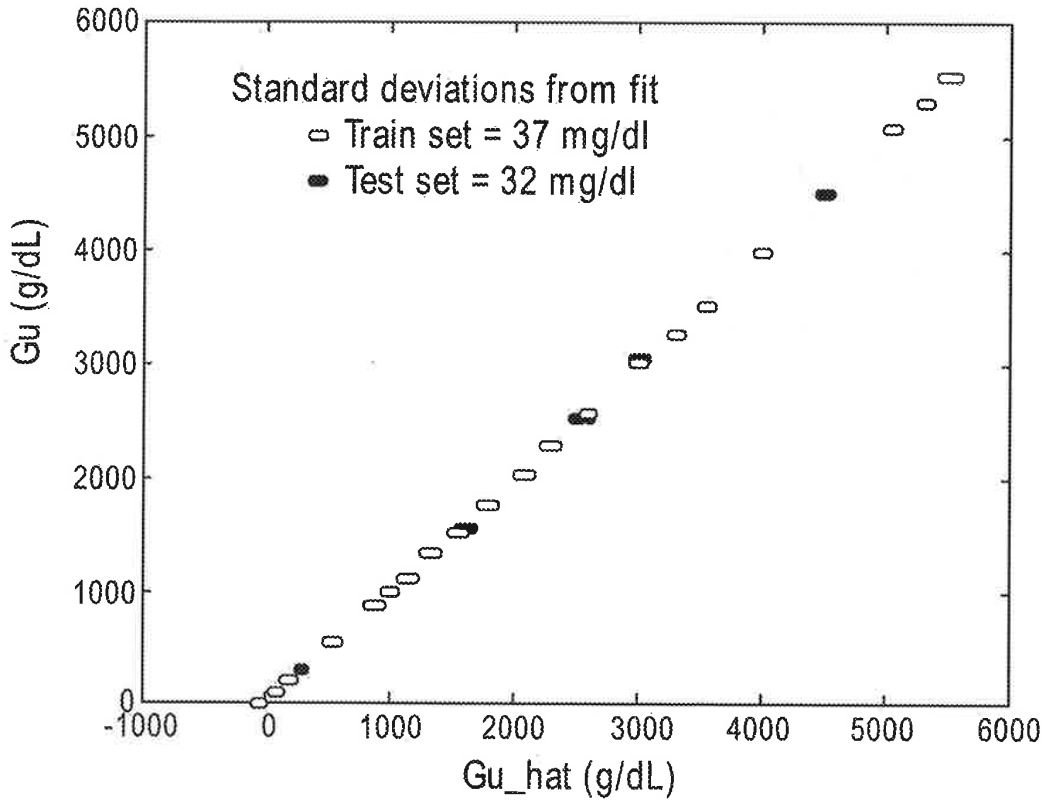


FIG. 19

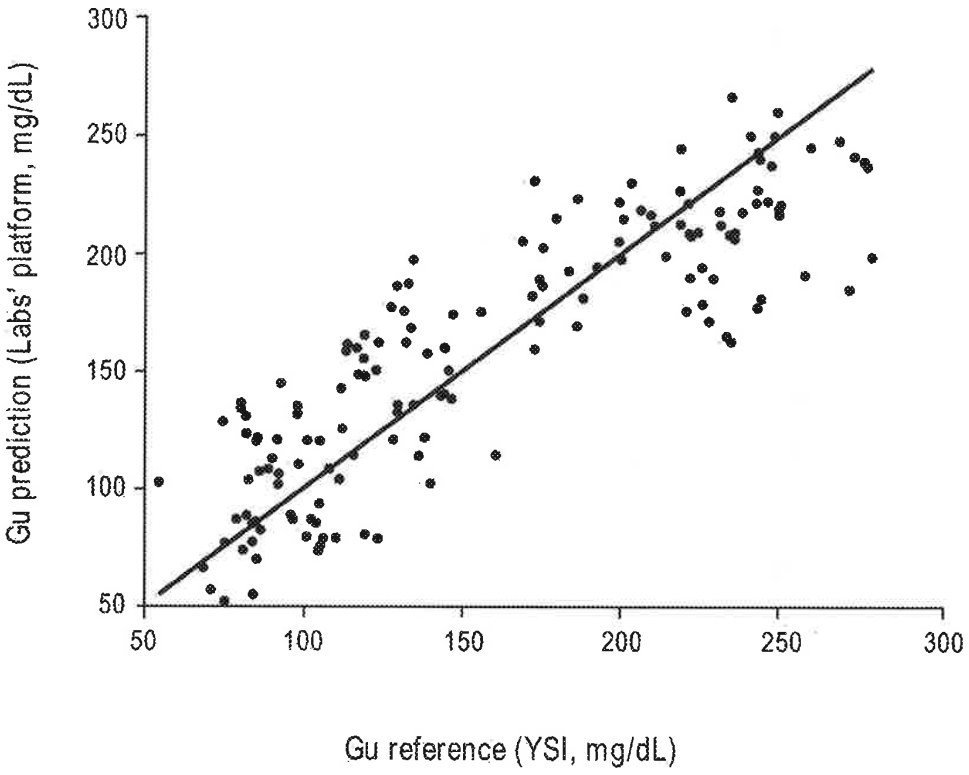


FIG. 20

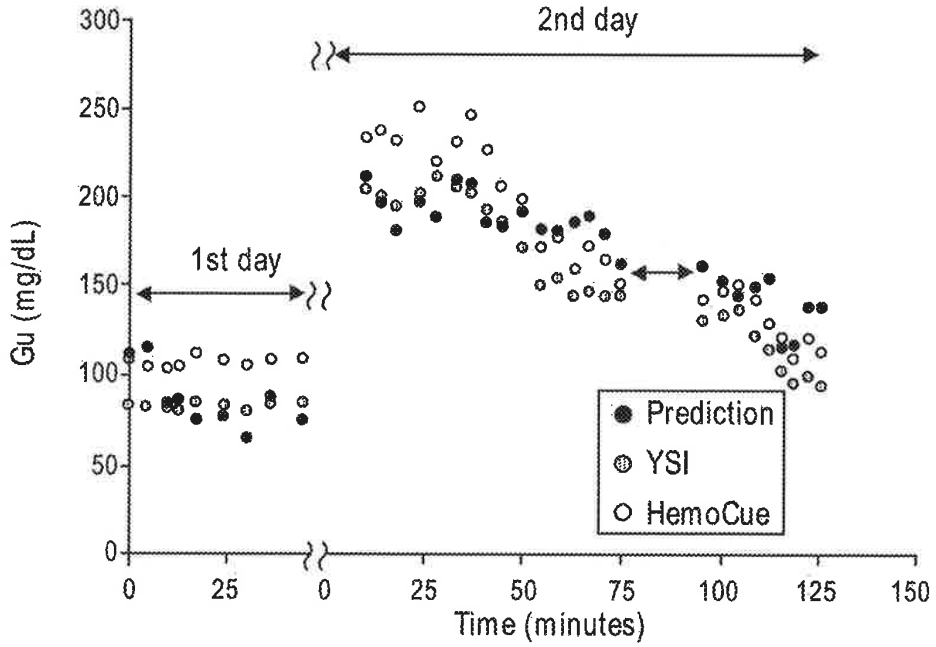


FIG. 21

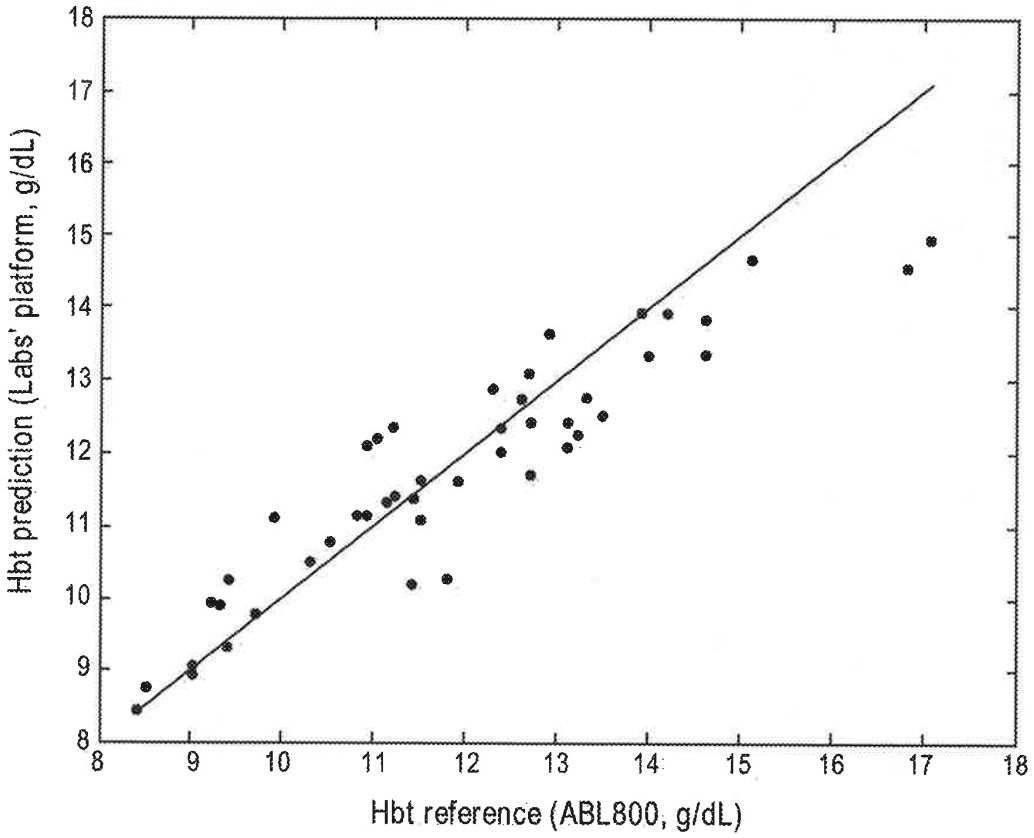


FIG. 22

USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. Patent Applications:

application Ser. No.	Filing Date	Title
12/497,528	Jul. 2, 2009	Noise Shielding for Noninvasive Device Contoured Protrusion for Improving
12/497,523	Jul. 2, 2009	Spectroscopic Measurement of Blood Constituents
12/497,506	Jul. 2, 2009	Heat Sink for Noninvasive Medical Sensor
12/534,812	Aug. 3, 2009	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents

-continued

application Ser. No.	Filing Date	Title
12/534,823	Aug. 3, 2009	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents
12/534,825	Aug. 3, 2009	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photodetection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal (s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from

said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at

sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. **1** illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. **2**A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. **1**, according to embodiments of the disclosure;

FIGS. **3**A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. **3**D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. **3**E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. **3**F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. **4**A through **4**C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

FIG. **5** illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. **6**A through **6**D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. **6**E illustrates an example sensor incorporating the protrusion of FIGS. **6**A through **6**D, according to an embodiment of the disclosure;

FIGS. **7**A through **7**B illustrate example arrangements of conductive glass that may be employed in the system of FIG. **1**, according to embodiments of the disclosure;

FIGS. **8**A through **8**D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. **1**, according to embodiments of the disclosure;

FIG. **9** shows example comparative results obtained by an embodiment of a sensor;

FIGS. **10**A and **10**B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. **11**A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. **11**B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. **11**C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. **11**D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. **12**A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. **12**B through **12**D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. **12**E through **12**H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. **13** illustrates an example multi-stream operation of the system of FIG. **1**, according to an embodiment of the disclosure;

FIG. **14**A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. **14**B depicts a front elevation view of the partially cylindrical protrusion of FIG. **14**A;

FIGS. **14**C through **14**E illustrate embodiments of a detector submount;

FIGS. **14**F through **14**H illustrate embodiment of portions of a detector shell;

FIG. **14**I illustrates a cutaway view of an embodiment of a sensor;

FIGS. **15**A through **15**F illustrate embodiments of sensors that include heat sink features;

FIGS. **15**G and **15**H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. **15**I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

FIG. **15**J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. **15**I;

FIG. **15**K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. **15**L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. **16**A and **16**B illustrate embodiments of disposable optical sensors;

FIG. **17** illustrates an exploded view of certain components of an example sensor; and

FIGS. **18** through **22** illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of noninvasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metalicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can

be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. **1** illustrates an example of a data collection system **100**. In certain embodiments, the data collection system **100** noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system **100** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system **100** can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system **100** can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm^2-5 mm^2 (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system **100** can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system **100** can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system **100** can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system **100** can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a

finger measurement site **102**. However, the features of the embodiments disclosed herein can be used with other measurement sites **102**.

In the depicted embodiment, the system **100** includes an optional tissue thickness adjuster or tissue shaper **105**, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper **105** is a flat or substantially flat surface that can be positioned proximate the measurement site **102** and that can apply sufficient pressure to cause the tissue of the measurement site **102** to be flat or substantially flat. In other embodiments, the tissue shaper **105** is a convex or substantially convex surface with respect to the measurement site **102**. Many other configurations of the tissue shaper **105** are possible. Advantageously, in certain embodiments, the tissue shaper **105** reduces thickness of the measurement site **102** while preventing or reducing occlusion at the measurement site **102**. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system **100** shown also includes an optional noise shield **103**. In an embodiment, the noise shield **103** can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site **102** to one or more detectors **106** (described below). For example, the noise shield **103** can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor **101** or electrically grounded. In an embodiment where the noise shield **103** includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site **102** is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system **100** can be used on a person's non-dominant hand or arm.

The data collection system **100** can include a sensor **101** (or multiple sensors) that is coupled to a processing device or physiological monitor **109**. In an embodiment, the sensor **101** and the monitor **109** are integrated together into a single unit. In another embodiment, the sensor **101** and the monitor **109** are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor **101** and monitor **109** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor **101** and the monitor **109** will now be further described.

In the depicted embodiment shown in FIG. **1**, the sensor **101** includes an emitter **104**, a tissue shaper **105**, a set of detectors **106**, and a front-end interface **108**. The emitter **104** can serve as the source of optical radiation transmitted towards measurement site **102**. As will be described in further detail below, the emitter **104** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **104** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter **104** is used as a point optical source, and thus, the one or more optical sources of the emitter **104** can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters **104** can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters **104** can be arranged at least in part as described in paragraphs **[0061]** through **[0068]** of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters **104**.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter **104** of the data collection system **100** can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter **104** can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter **104** can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter **104** can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter **104** can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter **104** can emit optical radiation across other spectra for other analytes. In particular, the emitter **104** can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter **104** can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about

1665 nm. In another embodiment, the emitter **104** can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter **104** can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system **100** can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter **104** can include sets of light-emitting diodes (LEDs) as its optical source. The emitter **104** can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter **104** can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter **104** can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter **104** can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter **104** can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO_2), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter **104** can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site **102**.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter **104** can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter **104** to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system **100** also includes a driver **111** that drives the emitter **104**. The driver **111** can be a circuit or the like that is controlled by the monitor **109**. For example, the driver **111** can provide pulses of current to the emitter **104**. In an embodiment, the driver **111** drives the emitter **104** in a progressive fashion, such as in an alternating manner. The driver **111** can drive the emitter **104** with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver **111** can be synchronized with other parts of the sensor **101** and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **104**. In some embodiments, the driver **111** is capable of driving the emitter **104** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors **106** capture and measure light from the measurement site **102**. For example, the detectors **106** can capture and measure light transmitted from the emitter **104** that has been attenuated or reflected from the tissue in the measurement site **102**. The detectors **106** can output a detector signal **107** responsive to the light captured or measured. The detectors **106** can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors **106** can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors **106**. That is, some of the detectors **106** can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter **104**. However, according to an embodiment, at least some of the detectors **106** can have a different path length from the emitter **104** relative to other of the detectors **106**. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors **106**. In some embodiments, the detectors **106** may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface **108** provides an interface that adapts the output of the detectors **106**, which is responsive to desired physiological parameters. For example, the front end interface **108** can adapt a signal **107** received from one or more of the detectors **106** into a form that can be processed by the monitor **109**, for example, by a signal processor **110** in the monitor **109**. The front end interface **108** can have its components assembled in the sensor **101**, in the monitor **109**, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface **108** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface **108** can be coupled to the detectors **106** and to the signal processor **110** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface **108** can also be at least partially integrated with various components, such as the detectors **106**. For example, the front end interface **108** can include one or more integrated circuits that are on the same circuit board as the detectors **106**. Other configurations can also be used.

The front end interface **108** can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor **109**), such as a sigma-delta ADC. A transimpedance-based front end interface **108** can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface **108** can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface **108**

can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter **104**.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor **110** of the monitor **109**. Each channel can correspond to a signal output from a detector **106**.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface **108**. For example, the output of a transimpedance-based front end interface **108** can be output to a PGA that is coupled with an ADC in the monitor **109**. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors **106**. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface **108** in the sensor **101**.

In another embodiment, the front end interface **108** can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface **108** can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface **108** can be useful because it can provide a digital signal to the signal processor **110** in the monitor **109**.

As shown in FIG. **1**, the monitor **109** can include the signal processor **110** and a user interface, such as a display **112**. The monitor **109** can also include optional outputs alone or in combination with the display **112**, such as a storage device **114** and a network interface **116**. In an embodiment, the signal processor **110** includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors **106**. The signal processor **110** can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **110** can provide various signals that control the operation of the sensor **101**. For example, the signal processor **110** can provide an emitter control signal to the driver **111**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **104**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **104** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface **108** is used, the control signal from the signal processor **110** can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **113** can be included in the front-end interface **108** and/or in the signal processor **110**. This memory **113** can serve as a buffer or storage location for the front-end interface **108** and/or the signal processor **110**, among other uses.

The user interface **112** can provide an output, e.g., on a display, for presentation to a user of the data collection system **100**. The user interface **112** can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface **112** can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface **112** can include a flip screen, a screen that can be moved from one side to another on the monitor **109**, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system **100** can be provided without a user interface **112** and can simply provide an output signal to a separate display or system.

A storage device **114** and a network interface **116** represent other optional output connections that can be included in the monitor **109**. The storage device **114** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **114**, which can be executed by the signal processor **110** or another processor of the monitor **109**. The network interface **116** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **109** to communicate and share data with other devices. The monitor **109** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **112**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system **100** can include various other components or can be configured in different ways. For example, the sensor **101** can have both the emitter **104** and detectors **106** on the same side of the measurement site **102** and use reflectance to measure analytes. The data collection system **100** can also include a sensor that measures the power of light emitted from the emitter **104**.

FIGS. **2A** through **2D** illustrate example monitoring devices **200** in which the data collection system **100** can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices **200** shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system **100**. In addition, certain of the features of the monitoring devices **200** shown in FIGS. **2A** through **2D** can be combined with features of the other monitoring devices **200** shown.

Referring specifically to FIG. **2A**, an example monitoring device **200A** is shown, in which a sensor **201***a* and a monitor **209***a* are integrated into a single unit. The monitoring device **200A** shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor **201***a* includes an emitter shell **204***a* and a detector shell **206***a*. The depicted embodiment of the monitoring device **200A** also includes various control buttons **208***a* and a display **210***a*.

The sensor **201***a* can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector **106** by forcing light back into the sensor **201***a*. Pads in the emitter shell **204***a* and the detector shell **206***a* can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell **204***a* and the detector shell **206***a* can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor **201***a*.

In some embodiments, some or all portions of the emitter shell **204***a* and/or detector shell **206***a* can be detachable and/or disposable. For example, some or all portions of the

shells **204***a* and **206***a* can be removable pieces. The removability of the shells **204***a* and **206***a* can be useful for sanitary purposes or for sizing the sensor **201***a* to different patients. The monitor **209***a* can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor **201***c* to be removably attached to the monitor **209***a*.

The monitoring device **200***a* also includes optional control buttons **208***a* and a display **210***a* that can allow the user to control the operation of the device. For example, a user can operate the control buttons **208***a* to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons **208***a* to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display **210***a*, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls **208***a* and/or display **210***a* can provide functionality for the user to manipulate settings of the monitoring device **200***a*, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device **200***a* can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. **2**B illustrates another example of a monitoring device **200**B. In the depicted embodiment, the monitoring device **200**B includes a finger clip sensor **201***b* connected to a monitor **209***b* via a cable **212**. In the embodiment shown, the monitor **209***b* includes a display **210***b*, control buttons **208***b* and a power button. Moreover, the monitor **209***b* can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor **201***b*, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable **212** connecting the sensor **201***b* and the monitor **209***b* can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable **212** can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor **201***b* to the monitor **209***b*. Various lengths of the cable **212** can be employed to allow for separation between the sensor **201***b* and the monitor **209***b*. The cable **212** can be fitted with a connector (male or female) on either end of the cable **212** so that the sensor **201***b* and the monitor **209***b* can be connected and disconnected from each other. Alternatively, the sensor **201***b* and the monitor **209***b* can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor **209***b* can be attached to the patient. For example, the monitor **209***b* can include a belt clip or straps (see, e.g., FIG. **2**C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor **209***b* can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable **212** and sensor **201***b* to be attached to the monitor **209**B.

The monitor **209***b* can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor **209***b* can include a display **210***b* that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor **209***b*.

In addition, although a single sensor **201***b* with a single monitor **209***b* is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. **2**C illustrates yet another example of monitoring device **200**C that can house the data collection system **100**. Like the monitoring device **200**B, the monitoring device **200**C includes a finger clip sensor **201***c* connected to a monitor **209***c* via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. **2**B. The monitor **209***c* can include all of the features of the monitor **200**B described above. For example, the monitor **209***c* includes buttons **208***c* and a display **210***c*. The monitor **209***c* shown also includes straps **214***c* that allow the monitor **209***c* to be attached to a patient's limb or the like.

FIG. **2**D illustrates yet another example of monitoring device **200**D that can house the data collection system **100**. Like the monitoring devices **200**B and **200**C, the monitoring device **200**D includes a finger clip sensor **201***d* connected to a monitor **209***d* via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. **2**B. In addition to having some or all of the features described above with respect to FIGS. **2**B and **2**C, the monitoring device **200**D includes an optional universal serial bus (USB) port **216** and an Ethernet port **218**. The USB port **216** and the Ethernet port **218** can be used, for example, to transfer information between the monitor **209***d* and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor **209***b*, and perform a variety of other functions. The USB port **216** and the Ethernet port **218** can be included with the other monitoring devices **200**A, **200**B, and **200**C described above.

FIGS. **3**A through **3**C illustrate more detailed examples of embodiments of a sensor **301***a*. The sensor **301***a* shown can include all of the features of the sensors **100** and **200** described above.

Referring to FIG. **3**A, the sensor **301***a* in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure **302***a* for receiving a patient's finger. The enclosure **302***a* is formed by an upper section or emitter shell **304***a*, which is pivotably connected with a lower section or detector shell **306***a*. The emitter shell **304***a* can be biased with the detector shell **306***a* to close together around a pivot point **303***a* and thereby sandwich finger tissue between the emitter and detector shells **304***a*, **306***a*.

In an embodiment, the pivot point **303***a* advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells **304***a*, **306***a* to effectively level the sections when applied to a tissue site. In another embodiment, the sensor **301***a* includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell **304***a* can position and house various emitter components of the sensor **301***a*. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell **304***a* can also include absorbing opaque mate-

rial, such as, for example, black or grey colored material, at various areas, such as on one or more flaps **307***a*, to reduce ambient light entering the sensor **301***a*.

The detector shell **306***a* can position and house one or more detector portions of the sensor **301***a*. The detector shell **306***a* can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. **1**). The detector shell **306***a* can also include absorbing opaque material at various areas, such as lower area **308***a*, to reduce ambient light entering the sensor **301***a*.

Referring to FIGS. **3**B and **3**C, an example of finger bed **310** is shown in the sensor **301***b*. The finger bed **310** includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed **310** includes one or more ridges or channels **314**. Each of the ridges **314** has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges **314** can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor **301***a*. The ridges **314** can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds **310**.

Finger bed **310** can also include an embodiment of a tissue thickness adjuster or protrusion **305**. The protrusion **305** includes a measurement site contact area **370** (see FIG. **3**C) that can contact body tissue of a measurement site. The protrusion **305** can be removed from or integrated with the finger bed **310**. Interchangeable, different shaped protrusions **305** can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. **3**C, the contact area **370** of the protrusion **305** can include openings or windows **320**, **321**, **322**, and **323**. When light from a measurement site passes through the windows **320**, **321**, **322**, and **323**, the light can reach one or more photodetectors (see FIG. **3**E). In an embodiment, the windows **320**, **321**, **322**, and **323** mirror specific detector placements layouts such that light can impinge through the protrusion **305** onto the photodetectors. Any number of windows **320**, **321**, **322**, and **323** can be employed in the protrusion **305** to allow light to pass from the measurement site to the photodetectors.

The windows **320**, **321**, **322**, and **323** can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows **320**, **321**, **322**, and **323** can be made from materials, such as plastic or glass. In some embodiments, the windows **320**, **321**, **322**, and **323** can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

Turning to FIG. **3**B, the sensor **301***a* can also include a shielding **315***a*, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding **315***a* is provided in the depicted embodiment below or embedded within the protrusion **305** to reduce noise. The shielding **315***a* can be constructed from a conductive material, such as copper. The shielding **315***a* can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows **320**, **321**, **322**, and **323** on an external surface of the protrusion **305** (see FIG. **3**C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. **3**E).

In some embodiments, the shielding cage for shielding **315***a* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion **305** (see FIG. **3**E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm^2 to about 60 mm^2 was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion **305** can be selected. In making such determinations, consideration can be made of protrusion's **305** effect on blood flow at the measurement site and mean path length for optical radiation passing through openings **320**, **321**, **322**, and **323**. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion **305** can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area **370** to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion **305** can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area **370**. The contact area **370** can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion **305** can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion **305** and the contact area **370** can include a combination of materials with various characteristics.

The contact area **370** serves as a contact surface for the measurement site. For example, in some embodiments, the contact area **370** can be shaped for contact with a patient's finger. Accordingly, the contact area **370** can be sized and shaped for different sizes of fingers. The contact area **370** can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example,

the contact area **370** can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. **5** provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. **5**, a plot **500** is shown that illustrates examples of effects of embodiments of the protrusion **305** on the SNR at various wavelengths of light. As described above, the protrusion **305** can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion **305** can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I=I_o*e^{-m*b*c}$, where I_o is the initial power of light being transmitted, m is the path length traveled by the light, and the component "b*c" corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1}. Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I=I_o*e^{(-20*0.7)}$.

In an embodiment where the protrusion **305** is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box **510**). This results in a new transmittance, $I_1=I_o*e^{(-16.6*0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot **500** of FIG. **5**. The plot **500** illustrates potential effects of the protrusion **305** on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6*0.7)}/e^{(-20*0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1}. The plot **500** also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. **3**A through **3**C, an example heat sink **350***a* is also shown. The heat sink **350***a* can be attached to, or protrude from an outer surface of, the sensor **301***a*, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor **301***a* in certain embodiments, the heat sink **350***a* can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. **1**) generate sufficient heat that inclusion of the heat sink **350***a* can advantageously allows the sensor **301***a* to remain safely cooled. The heat sink **350***a* can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell **304***a* can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink **350***a* includes metalicized plastic. The metalicized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink **350***a* can include a thermally conductive liquid crystalline polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, R.I. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink **350***a* provides improved heat transfer properties when the sensor **301***a* is active for short intervals of less than a full day's use. In an embodiment, the heat sink **350***a* can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink **350***a* can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink **350***a* can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink **350***a* is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink **350***a* shown includes fins **351***a* (see FIG. **3**A).

An alternative shape of a sensor **301***b* and heat sink **350***b* is shown in FIG. **3**D. The sensor **301***b* can include some or all of the features of the sensor **301***a*. For example, the sensor **301***b* includes an enclosure **302***b* formed by an emitter shell **304***b* and a detector shell **306***b*, pivotably connected about a pivot **303***a*. The emitter shell **304***b* can also include absorbing opaque material on one or more flaps **307***b*, and the detector shell **306***a* can also include absorbing opaque material at various areas, such as lower area **308***b*.

However, the shape of the sensor **301***b* is different in this embodiment. In particular, the heat sink **350***b* includes comb protrusions **351***b*. The comb protrusions **351***b* are exposed to the air in a similar manner to the fins **351***a* of the heat sink **350***a*, thereby facilitating efficient cooling of the sensor **301***b*.

FIG. **3**E illustrates a more detailed example of a detector shell **306***b* of the sensor **301***b*. The features described with respect to the detector shell **306***b* can also be used with the detector shell **306***a* of the sensor **301***a*.

As shown, the detector shell **306***b* includes detectors **316**. The detectors **316** can have a predetermined spacing **340** from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors **316** and the emitter discussed above.

In the depicted embodiment, the detector shell **316** can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site **102**). In the detector shell **316**, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell **316** can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. **3**E, the detectors **316** can have a spatial configuration of a grid. However, the detectors **316** can be arranged in other configurations that vary the path length. For example, the detectors **316** can be arranged in a linear array, a logarithmic array, a two-dimensional

array, a zig-zag pattern, or the like. Furthermore, any number of the detectors **316** can be employed in certain embodiments.

FIG. **3**F illustrates another embodiment of a sensor **301***f*. The sensor **301***f* can include some or all of the features of the sensor **301***a* of FIG. **3**A described above. For example, the sensor **301***f* includes an enclosure **302***f* formed by an upper section or emitter shell **304***f*, which is pivotably connected with a lower section or detector shell **306***f* around a pivot point **303***f*. The emitter shell **304***f* can also include absorbing opaque material on various areas, such as on one or more flaps **307***f*, to reduce ambient light entering the sensor **301***f*. The detector shell **306***f* can also include absorbing opaque material at various areas, such as a lower area **308***f*. The sensor **301***f* also includes a heat sink **350***f*, which includes fins **351***f*.

In addition to these features, the sensor **301***f* includes a flex circuit cover **360**, which can be made of plastic or another suitable material. The flex circuit cover **360** can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell **304***f* to the detector shell **306***f*. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. **46** and associated description, which is hereby specifically incorporated by reference). The flex circuit cover **360** is shown in more detail below in FIG. **17**.

In addition, sensors **301***a-f* has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. **4**A through **4**C illustrate example arrangements of a protrusion **405**, which is an embodiment of the protrusion **305** described above. In an embodiment, the protrusion **405** can include a measurement site contact area **470**. The measurement site contact area **470** can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion **405** can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion **405** can have a length **400**, a width **410**, and a height **430**. The length **400** can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width **410** can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height **430** can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions **400**, **410**, and **430** can be selected such that the measurement site contact area **470** includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area **470** can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area **470** can be generally curved and/or convex with respect to the measurement site. The measurement site contact area **470** can be other shapes that reduce or even minimize air between the protrusion **405** and/or the measurement site. Additionally, the surface pattern of the measurement site contact area **470** can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. **4**A and **4**C, openings or windows **420**, **421**, **422**, and **423** can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows **420**, **421**, **422**, and **423** can be of non-uniform shapes and sizes. As shown, the windows **420**, **421**, **422**, and **423** can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows **420**, **421**, **422**, and **423** are possible. For example, the windows **420**, **421**, **422**, and **423** can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows **420**, **421**, **422**, and **423** can be placed at different heights with respect to the finger bed **310** of FIG. **3**. The windows **420**, **421**, **422**, and **423** can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. **6**A through **6**D illustrate another embodiment of a protrusion **605** that can be used as the tissue shaper **105** described above or in place of the protrusions **305**, **405** described above. The depicted protrusion **605** is a partially cylindrical lens having a partial cylinder **608** and an extension **610**. The partial cylinder **608** can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion **605** focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. **6**A illustrates a perspective view of the partially cylindrical protrusion **605**. FIG. **6**B illustrates a front elevation view of the partially cylindrical protrusion **605**. FIG. **6**C illustrates a side view of the partially cylindrical protrusion **605**. FIG. **6**D illustrates a top view of the partially cylindrical protrusion **605**.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion **605** over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion **605** penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion **605** can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion **605** can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. **14**). If fewer or smaller photodiodes are used, the partially cylindrical protrusion **605** can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion **605** can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. **6**C, the overall height of the partially cylindrical protrusion **605** (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion **605** to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion **605** can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion **605** is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. **6**D, the width of the partially cylindrical protrusion **605** (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration

of the partially cylindrical protrusion **605** into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the width of the partially cylindrical protrusion **605** can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion **605** could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially

$$f = \frac{R}{n-1},$$

cylindrical protrusion **605** can be expressed as: where R is the radius of curvature of the partial cylinder **608** and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion **605** can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion **605** having a material with a higher index of refraction such as nSF11 glass (e.g., n=1.75 at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion **605** can be chosen to improve or optimize the light focusing properties of the protrusion **605**. A plastic partially cylindrical protrusion **605** could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion **605**.

Placing a photodiode at a given distance below the partially cylindrical protrusion **605** can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. **14**). Different sizes of the partially cylindrical protrusion **605** can use different sizes of photodiodes. The extension **610** added onto the bottom of the partial cylinder **608** is used in certain embodiments to increase the height of the partially cylindrical protrusion **605**. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion **605**. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension **610** can also further facilitate the protrusion **605** increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension **610** can be omitted.

FIG. **6**E illustrates another view of the sensor **301***f* of FIG. **3**F, which includes an embodiment of a partially cylindrical protrusion **605***b*. Like the sensor **301**A shown in FIGS. **3**B and **3**C, the sensor **301***f* includes a finger bed **310***f*. The finger bed **310***f* includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed **310***f* also includes the ridges or channels **314** described above with respect to FIGS. **3**B and **3**C.

The example of finger bed **310***f* shown also includes the protrusion **605***b*, which includes the features of the protrusion **605** described above. In addition, the protrusion **605***b* also includes chamfered edges **607** on each end to provide a more comfortable surface for a finger to slide across (see also FIG. **14**D). In another embodiment, the protrusion **605***b* could instead include a single chamfered edge **607** proximal to the ridges **314**. In another embodiment, one or both of the chamfered edges **607** could be rounded.

The protrusion **605***b* also includes a measurement site contact area **670** that can contact body tissue of a measurement site. The protrusion **605***b* can be removed from or integrated with the finger bed **310***f*. Interchangeable, differently shaped protrusions **605***b* can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. **7**A and **7**B illustrate block diagrams of sensors **701** that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors **701** can be implemented with any of the sensors **101**, **201**, **301** described above. Although not shown, the partially cylindrical protrusion **605** of FIG. **6** can also be used with the sensors **701** in certain embodiments.

For example, referring specifically to FIG. **7**A, the sensor **701***a* includes an emitter housing **704***a* and a detector housing **706**. The emitter housing **704***a* includes LEDs **104**. The detector housing **706***a* includes a tissue bed **710***a* with an opening or window **703***a*, the conductive glass **730***a*, and one or more photodiodes for detectors **106** provided on a submount **707***a*.

During operation, a finger **102** can be placed on the tissue bed **710***a* and optical radiation can be emitted from the LEDs **104**. Light can then be attenuated as it passes through or is reflected from the tissue of the finger **102**. The attenuated light can then pass through the opening **703***a* in the tissue bed **710***a*. Based on the received light, the detectors **106** can provide a detector signal **107**, for example, to the front end interface **108** (see FIG. **1**).

In the depicted embodiment, the conductive glass **730** is provided in the opening **703**. The conductive glass **730** can thus not only permit light from the finger to pass to the detectors **106**, but it can also supplement the shielding of the detectors **106** from noise. The conductive glass **730** can include a stack or set of layers. In FIG. **7**A, the conductive glass **730***a* is shown having a glass layer **731** proximate the finger **102** and a conductive layer **733** electrically coupled to the shielding **790***a*.

In an embodiment, the conductive glass **730***a* can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure **790***a*, the conductive glass **730***a* can be electrically coupled to the shielding enclosure **790***a*. The conductive glass **730***a* can be electrically coupled to the shielding **704***a* based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure **790***a* can be provided to encompass the detectors **106** to reduce or prevent noise. For example, the shielding enclosure **790***a* can be constructed from a conductive material, such as copper, in the form of a

metal cage. The shielding or enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure **790***a* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790***a* can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

Referring to FIG. **7**B, another block diagram of an example sensor **701***b* is shown. A tissue bed **710***b* of the sensor **701***b* includes a protrusion **705***b*, which is in the form of a convex bump. The protrusion **705***b* can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion **705***b* includes a contact area **370** that comes in contact with the finger **102** and which can include one or more openings **703***b*. One or more components of conductive glass **730***b* can be provided in the openings **703**. For example, in an embodiment, each of the openings **703** can include a separate window of the conductive glass **730***b*. In an embodiment, a single piece of the conductive glass **730***b* can used for some or all of the openings **703***b*. The conductive glass **730***b* is smaller than the conductive glass **730***a* in this particular embodiment.

A shielding enclosure **790***b* is also provided, which can have all the features of the shielding enclosure **790***a*. The shielding enclosure **790***b* is smaller than the shielding enclosure **790***a*; however, a variety of sizes can be selected for the shielding enclosures **790**.

In some embodiments, the shielding enclosure **790***b* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790***b* can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

FIGS. **8**A through **8**D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors **701***a*, **701***b*. As shown in the perspective view of FIG. **8**A and side view of FIG. **8**B, the conductive glass **730** includes the electrically conductive material **733** described above as a coating on the glass layer **731** described above to form a stack. In an embodiment where the electrically conductive material **733** includes indium tin oxide, surface resistivity of the electrically conductive material **733** can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material **733**.

Although the conductive material **733** is shown spread over the surface of the glass layer **731**, the conductive material **733** can be patterned or provided on selected portions of the glass layer **731**. Furthermore, the conductive material **733** can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. **8**C, a side view of a conductive glass **830***a* is shown to illustrate an embodiment where the electrically conductive material **733** is provided as an internal layer between two glass layers **731**, **835**. Various combinations of integrating electrically conductive material **733** with glass are possible. For example, the electrically conductive material **733** can be a layer within a stack of layers. This stack of layers can include one or more layers of glass **731**, **835**, as well as one or more layers of conductive material **733**. The stack can include other layers of materials to achieve desired characteristics.

In FIG. **8**D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass **830***b* can include conductive material **837** that occupies or covers a portion of a glass layer **839**. This embodiment can be useful, for example, to create individual, shielded windows for detectors **106**, such as those shown in FIG. **3**C. The conductive material **837** can be patterned to include an area **838** to allow light to pass to detectors **106** and one or more strips **841** to couple to the shielding **704** of FIG. **7**.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. **9** depicts an example graph **900** that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. **7** and **8**. The graph **900** depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line **915** on the graph **900** illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line **920** on the graph **900** demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line **925** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line **930** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. **10**A through **10**B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. **10**A, a graph **1000** depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above

included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. **10**B, a graph **1050** depicts a noise floor for frequencies of noise **1070** for an embodiment in which the sensor included separate openings for four (4) detectors **106** and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols **1080-1083** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. **10**A.

FIG. **11**A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter **104** can include a driver **1105**, a thermistor **1120**, a set of top-emitting LEDs **1102** for emitting red and/or infrared light, a set of side-emitting LEDs **1104** for emitting near infrared light, and a submount **1106**.

The thermistor **1120** can be provided to compensate for temperature variations. For example, the thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement cite. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver **1105** can provide pulses of current to the emitter **1104**. In an embodiment, the driver **1105** drives the emitter **1104** in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor **110**). For example, the driver **1105** can drive the emitter **1104** with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver **1105** can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter **1104**. In some embodiments, the driver **1105** is capable of driving the emitter **1104** to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount **1106** provides a support structure in certain embodiments for aligning the top-emitting LEDs **1102** and the side-emitting LEDs **1104** so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount **1106** is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount **1106** can be used.

FIG. **11**B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter **104** may be driven in a progressive fashion to minimize noise and increase SNR of sensor **101**. For example, emitter **104** may be driven based on a progression of power/current delivered to LEDs **1102** and **1104**.

In some embodiments, emitter **104** may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter **104** may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter **104** may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. **11**B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs **1102**. FIG. **11**B also shows that emitter **104** may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs **1104**. Emitter **104** may be progressively driven at higher power/current. This progression may allow driver circuit **105** to stabilize in its operations, and thus, provide a more stable current/power to LEDs **1102** and **1104**.

For example, as shown in FIG. **11**B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs **1102** may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs **1104** (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit **1105** to stabilize after operating at higher current/power.

As shown in FIG. **11**B, top emitting LEDs **1102** may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs **1102** may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs **502** for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter **104**.

Subsequently, side emitting LEDs **1104** may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site **102** to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment,

the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs **1104**. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter **104**.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit **1105** to stabilize its power delivery to LEDs **1102** and **1104**. Driver circuit **1105** may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit **1105**. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system **100**. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit **1105** may monitor temperatures of the LEDs **1102** and **1104** using the thermistor **1120** and adjust the output of LEDs **1102** and **1104** accordingly. Such a temperature may be to help sensor **101** correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. **11**C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter **104** can include components mounted on a substrate **1108** and on submount **1106**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**. Side emitting LEDS **1104** may be mounted on submount **1106**. As noted, side-emitting LEDs **1104** may be included in emitter **104** for emitting near infrared light.

As also shown, the sensor of FIG. **11**C may include a thermistor **1120**. As noted, the thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter **104** may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. **11**D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter **104** that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter **104** can include components mounted on a substrate **1108**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**.

As also shown, the emitter of FIG. **11**D may include a thermistor **1120**. The thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** due to heating.

FIG. **12**A illustrates a detector submount **1200** having photodiode detectors that are arranged in a grid pattern on the detector submount **1200** to capture light at different quadrants from a measurement site. One detector submount **1200** can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount **1200**. The detector submount **1200** can also be used with the partially cylindrical protrusion **605** described above with respect to FIG. **6**.

The detectors include photodiode detectors **1-4** that are arranged in a grid pattern on the submount **1200** to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors **1-4** may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors **106** and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site **102**). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. **12**B through **12**D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors **106**. As shown, detectors **106** may comprise photodiode detectors **1-4** that are arranged in a grid pattern on detector submount **1200** to capture light at different quadrants from measurement site **102**.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors **106** may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors **106** may be employed by embodiments of the present disclosure.

For example, as shown in FIG. **12**B, detectors **106** may comprise photodiode detectors **1-4** that are arranged in a substantially linear configuration on submount **1200**. In this embodiment shown, photodiode detectors **1-4** are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors **1-4**).

In FIG. **12**C, photodiode detectors **1-4** may be arranged in a substantially linear configuration on submount **1200**, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances D1>D2>D3). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. **12**D, a different substantially grid pattern on submount **1200** of photodiode detectors **1-4** is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. **12**E through **12**H illustrate several embodiments of photodiodes that may be used in detectors **106**. As shown in

these figures, a photodiode **1202** of detector **106** may comprise a plurality of active areas **1204**. These active areas **204** may be coupled together via a common cathode **1206** or anode **1208** in order to provide a larger effective detection area.

In particular, as shown in FIG. **12**E, photodiode **1202** may comprise two (2) active areas **1204***a* and **1204***b*. In FIG. **12**F, photodiode **1202** may comprise four (4) active areas **1204***c-f*. In FIG. **12**G, photodiode **1202** may comprise three (3) active areas **1204***g-i*. In FIG. **12**H, photodiode **1202** may comprise nine (9) active areas **1204***j-r*. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode **1202**.

FIG. **13** illustrates an example multi-stream process **1300**. The multi-stream process **1300** can be implemented by the data collection system **100** and/or by any of the sensors described above. As shown, a control signal from a signal processor **1310** controls a driver **1305**. In response, an emitter **1304** generates a pulse sequence **1303** from its emitter (e.g., its LEDs) into a measurement site or sites **1302**. As described above, in some embodiments, the pulse sequence **1303** is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence **1303** can be greater (or smaller).

In response to the pulse sequence **1300**, detectors **1** to n (n being an integer) in a detector **1306** capture optical radiation from the measurement site **1302** and provide respective streams of output signals. Each signal from one of detectors **1**-*n* can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets **1**-*n* in the emitter **1304**. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface **1308** can accept these multiple streams from detectors **1**-*n* and deliver one or more signals or composite signal(s) back to the signal processor **1310**. A stream from the detectors **1**-*n* can thus include measured light intensities corresponding to the light pulses emitted from the emitter **1304**.

The signal processor **1310** can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor **1310** can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

$$\text{Absorbance } A = m*b*c, \text{ where:}$$

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of M^{-1} cm^{-1});

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$T=I/I_o$, where:

I is the light intensity measured by the instrument from the measurement site; and

I_o is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A=-\log T$$

Therefore, substituting equations from above:

$$A=-\log(I/I_o)$$

In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_o)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_o), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude that what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T=e^{-m*b*c}$$

In terms of light intensity, this equation can also be rewritten as:

$$I/I_o=e^{-m*b*c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I=I_o*e^{-m*b*c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \ldots I_n$ streams of measurements. Assuming each of these detectors have their own path lengths, $b_1 \ldots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n=I_o*e^{-m*b_n*c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n=(I_o*e^{-mb_1c})/(I_o*e^{-mb_nc})$$

As can be seen, the terms, I_o, cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n=e^{-m(b_1-b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \ldots I_n$ and knowing the respective mean path lengths b_1 and b_n. This scheme also allows for the cancelling out of I_o, and thus, noise generated by the emitter **1304** can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) **1302**. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. **14**A illustrates an embodiment of a detector submount **1400***a* positioned beneath the partially cylindrical protrusion **605** of FIG. **6** (or alternatively, the protrusion **605***b*). The detector submount **1400***a* includes two rows **1408***a* of detectors **1410***a*. The partially cylindrical protrusion **605** can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion **605** can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion **605**, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion **605** to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion **605** (see FIG. **14**B). This is the example situation illustrated in FIG. **14**—two rows **1408***a* of detectors **1410***a* are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion **605** can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. **14**B depicts a front elevation view of the partially cylindrical protrusion **605** (or alternatively, the protrusion **605***b*) that illustrates how light from emitters (not shown) can be focused by the protrusion **605** onto detectors. The protrusion **605** is placed above a detector submount **1400***b* having one or more detectors **1410***b* disposed thereon. The submount **1400***b* can include any number of rows of detectors **1410**, although one row is shown.

Light, represented by rays **1420**, is emitted from the emitters onto the protrusion **605**. These light rays **1420** can be attenuated by body tissue (not shown). When the light rays **1420** enter the protrusion **605**, the protrusion **605** acts as a lens to refract the rays into rays **1422**. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion **605**. The refraction causes the rays **1422** to be focused or substantially focused on the one or more detectors **1410***b*. Since the light is focused on a smaller area, a sensor including the protrusion **605** can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. **14**C illustrates another embodiment of a detector submount **1400***c*, which can be disposed under the protrusion **605***b* (or alternatively, the protrusion **605**). The detector submount **1400***c* includes a single row **1408***c* of detectors **1410***c*. The detectors are electrically connected to conductors **1412***c*, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount **1400***c* is shown positioned under the protrusion **605***b* in a detector subassembly **1450** illustrated in FIG. **14**D. A top-down view of the detector subassembly **1450** is also shown in FIG. **14**E. In the detector subassembly **1450**, a cylindrical housing **1430** is disposed on the submount **1400***c*. The cylindrical housing **1430** includes a transparent cover **1432**, upon which the protrusion **605***b* is disposed. Thus, as shown in FIG. **14**D, a gap **1434** exists between the detectors **1410***c* and the protrusion **605***b*. The height of this gap **1434** can be chosen to increase or maximize the amount of light that impinges on the detectors **1410***c*.

The cylindrical housing **1430** can be made of metal, plastic, or another suitable material. The transparent cover **1432** can be fabricated from glass or plastic, among other materials. The cylindrical housing **1430** can be attached to the submount **1400***c* at the same time or substantially the same time as the detectors **1410***c* to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing **1430** in various embodiments.

In certain embodiments, the cylindrical housing **1430** (and transparent cover **1432**) forms an airtight or substantially airtight or hermetic seal with the submount **1400***c*. As

a result, the cylindrical housing **1430** can protect the detectors **1410***c* and conductors **1412***c* from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing **1430** can protect the detectors **1410***c* and conductors **1412***c* more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing **1430** is at least partially made of metal, the cylindrical housing **1430** can provide noise shielding for the detectors **1410***c*. For example, the cylindrical housing **1430** can be soldered to a ground connection or ground plane on the submount **1400***c*, which allows the cylindrical housing **1430** to reduce noise. In another embodiment, the transparent cover **1432** can include a conductive material or conductive layer, such as conductive glass or plastic. The transparent cover **1432** can include any of the features of the noise shields **790** described above.

The protrusion **605***b* includes the chamfered edges **607** described above with respect to FIG. **6**E. These chamfered edges **607** can allow a patient to more comfortably slide a finger over the protrusion **605***b* when inserting the finger into the sensor **301***f*.

FIG. **14**F illustrates a portion of the detector shell **306***f*, which includes the detectors **1410***c* on the substrate **1400***c*. The substrate **1400***c* is enclosed by a shielding enclosure **1490**, which can include the features of the shielding enclosures **790***a*, **790***b* described above (see also FIG. **17**). The shielding enclosure **1490** can be made of metal. The shielding enclosure **1490** includes a window **1492***a* above the detectors **1410***c*, which allows light to be transmitted onto the detectors **1410***c*.

A noise shield **1403** is disposed above the shielding enclosure **1490**. The noise shield **1403**, in the depicted embodiment, includes a window **1492***a* corresponding to the window **1492***a*. Each of the windows **1492***a*, **1492***b* can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows **1492***a*, **1492***b* may be selected to have different sizes or shapes from each other.

The noise shield **1403** can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield **1403** extends about three-quarters of the length of the detector shell **306***f*. In other embodiments, the noise shield **1403** could be smaller or larger. The noise shield **1403** could, for instance, merely cover the detectors **1410***c*, the submount **1400***c*, or a portion thereof. The noise shield **1403** also includes a stop **1413** for positioning a measurement site within the sensor **301***f*. Advantageously, in certain embodiments, the noise shield **1403** can reduce noise caused by light piping.

A thermistor **1470** is also shown. The thermistor **1470** is attached to the submount **1400***c* and protrudes above the noise shield **1403**. As described above, the thermistor **1470** can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors **1410***c* are not enclosed in the cylindrical housing **1430**. In an alternative embodiment, the cylindrical housing **1430** encloses the detectors **1410***c* and is disposed under the noise shield **1403**. In another embodiment, the cylindrical housing **1430** encloses the detectors **1410***c* and the noise shield **1403** is not used. If both the cylindrical housing **1403** and the noise shield **1403** are used, either or both can have noise shielding features.

FIG. **14**G illustrates the detector shell **306***f* of FIG. **14**F, with the finger bed **310***f* disposed thereon. FIG. **14**H illustrates the detector shell **306***f* of FIG. **14**G, with the protrusion **605***b* disposed in the finger bed **310***f*.

FIG. **14**I illustrates a cutaway view of the sensor **301***f*. Not all features of the sensor **301***f* are shown, such as the protrusion **605***b*. Features shown include the emitter and detector shells **304***f*, **306***f*, the flaps **307***f*, the heat sink **350***f* and fins **351***f*, the finger bed **310***f*, and the noise shield **1403**.

In addition to these features, emitters **1404** are depicted in the emitter shell **304***f*. The emitters **1404** are disposed on a submount **1401**, which is connected to a circuit board **1419**. The emitters **1404** are also enclosed within a cylindrical housing **1480**. The cylindrical housing **1480** can include all of the features of the cylindrical housing **1430** described above. For example, the cylindrical housing **1480** can be made of metal, can be connected to a ground plane of the submount **1401** to provide noise shielding, and can include a transparent cover **1482**.

The cylindrical housing **1480** can also protect the emitters **1404** from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing **1480** can provide a gap between the emitters **1404** and the measurement site (not shown), which can allow light from the emitters **1404** to even out or average out before reaching the measurement site.

The heat sink **350***f*, in addition to including the fins **351***f*, includes a protuberance **352***f* that extends down from the fins **351***f* and contacts the submount **1401**. The protuberance **352***f* can be connected to the submount **1401**, for example, with thermal paste or the like. The protuberance **352***f* can sink heat from the emitters **1404** and dissipate the heat via the fins **351***f*.

FIGS. **15**A and **15**B illustrate embodiments of sensor portions **1500**A, **1500**B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions **1500**A, **1500**B shown include LED emitters **1504**; however, for ease of illustration, the detectors have been omitted. The sensor portions **1500**A, **1500**B shown can be included, for example, in any of the emitter shells described above.

The LEDs **1504** of the sensor portions **1500**A, **1500**B are connected to a substrate or submount **1502**. The submount **1502** can be used in place of any of the submounts described above. The submount **1502** can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable **1512** is attached to the submount **1502** and includes electrical wiring **1514**, such as twisted wires and the like, for communicating with the LEDs **1504**. The cable **1512** can correspond to the cables **212** described above.

Although not shown, the cable **1512** can also include electrical connections to a detector. Only a portion of the cable **1512** is shown for clarity. The depicted embodiment of the cable **1512** includes an outer jacket **1510** and a conductive shield **1506** disposed within the outer jacket **1510**. The conductive shield **1506** can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield **1506** or a portion of the conductive shield **1506** can be electrically connected to the submount

1502 and can reduce noise in the signal generated by the sensor **1500**A, **1500**B by reducing RF coupling with the wires **1514**. In alternative embodiments, the cable **1512** does not have a conductive shield. For example, the cable **1512** could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. **15**A, in certain embodiments, the conductive shield **1506** can act as a heat sink for the LEDs **1504** by absorbing thermal energy from the LEDs **1504** and/or the submount **1502**. An optional heat insulator **1520** in communication with the submount **1502** can also assist with directing heat toward the conductive shield **1506**. The heat insulator **1520** can be made of plastic or another suitable material. Advantageously, using the conductive shield **1506** in the cable **1512** as a heat sink can, in certain embodiments, reduce cost for the sensor.

Referring to FIG. **15**B, the conductive shield **1506** can be attached to both the submount **1502** and to a heat sink layer **1530** sandwiched between the submount **1502** and the optional insulator **1520**. Together, the heat sink layer **1530** and the conductive shield **1506** in the cable **1512** can absorb at least part of the thermal energy from the LEDs and/or the submount **1502**.

FIGS. **15**C and **15**D illustrate implementations of a sensor portion **1500**C that includes the heat sink features of the sensor portion **1500**A described above with respect to FIG. **15**A. The sensor portion **1500**C includes the features of the sensor portion **1500**A, except that the optional insulator **1520** is not shown. FIG. **15**D is a side cutaway view of the sensor portion **1500**C that shows the emitters **1504**.

The cable **1512** includes the outer jacket **1510** and the conductive shield **1506**. The conductive shield **1506** is soldered to the submount **1502**, and the solder joint **1561** is shown. In some embodiments, a larger solder joint **1561** can assist with removing heat more rapidly from the emitters **1504**. Various connections **1563** between the submount **1502** and a circuit board **1519** are shown. In addition, a cylindrical housing **1580**, corresponding to the cylindrical housing **1480** of FIG. **14**I, is shown protruding through the circuit board **1519**. The emitters **1504** are enclosed in the cylindrical housing **1580**.

FIGS. **15**E and **15**F illustrate implementations of a sensor portion **1500**E that includes the heat sink features of the sensor portion **1500**B described above with respect to FIG. **15**B. The sensor portion **1500**E includes the heat sink layer **1530**. The heat sink layer **1530** can be a metal plate, such as a copper plate or the like. The optional insulator **1520** is not shown. FIG. **15**F is a side cutaway view of the sensor portion **1500**E that shows the emitters **1504**.

In the depicted embodiment, the conductive shield **1506** of the cable **1512** is soldered to the heat sink layer **1530** instead of the submount **1502**. The solder joint **1565** is shown. In some embodiments, a larger solder joint **1565** can assist with removing heat more rapidly from the emitters **1504**. Various connections **1563** between the submount **1502** and a circuit board **1519** are shown. In addition, the cylindrical housing **1580** is shown protruding through the circuit board **1519**. The emitters **1504** are enclosed in the cylindrical housing **1580**.

FIGS. **15**G and **15**H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. **1** through **15**F. Referring to FIG. **15**G, the circuit board **1519** includes a female connector **1575** that mates with a male connector **1577** connected to a daughter board **1587**. The daughter board **1587** includes connections to the electrical wiring **1514** of the cable **1512**. The connected boards **1519**, **1587** are shown in FIG. **15**H. Also shown is a hole **1573** that can receive the cylindrical housing **1580** described above.

Advantageously, in certain embodiments, using a daughter board **1587** to connect to the circuit board **1519** can enable connections to be made more easily to the circuit board **1519**. In addition, using separate boards can be easier to manufacture than a single circuit board **1519** with all connections soldered to the circuit board **1519**.

FIG. **15**I illustrates an exemplary architecture for front-end interface **108** as a transimpedance-based front-end. As noted, front-end interfaces **108** provide an interface that adapts the output of detectors **106** into a form that can be handled by signal processor **110**. As shown in this figure, sensor **101** and front-end interfaces **108** may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor **101** and front end interfaces **108** may comprise multiple components or circuits that are coupled together.

Front-end interfaces **108** may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors **106**. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter **900** may be integrated with the transimpedance-based front-end in sensor **101**.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector **106**, the applicants developed a noise model to assist in configuring front-end **108**. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise}=\sqrt{aR+bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector **106**.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors **1-4** (as shown, e.g., in FIG. **12**A) may each comprise four photodiodes. In some embodiments, each detector of four

photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. **15**J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors **1-4**. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in FIG. **15**J.

As yet another alternative, as noted above with respect to FIGS. **12**E through **12**H, the photodiodes in detectors **106** may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. **15**J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary "4 PD per stream" sensor **1502** is shown where detector **106** comprises four photodiodes **1502**. The photodiodes **1502** are coupled to a single transimpedance amplifier **1504** to produce an output stream **1506**. In this example, the transimpedance amplifier comprises 10 MΩ resistors **1508** and **1510**. Thus, output stream **1506** is produced from the four photodiodes (PD) **1502**. As shown in the graph of FIG. **15**J, the model indicates that resistance values of about 10 MΩ may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary "1 PD per stream" sensor **1512** is also shown in FIG. **15**J. In particular, sensor **1512** may comprise a plurality of detectors **106** that each comprises a single photodiode **1514**. In addition, as shown for this example configuration, each of photodiodes **1514** may be coupled to respective transimpedance amplifiers **1516**, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 MΩ resistors **1518**. As also shown in the graph of FIG. **15**J, the model illustrates that resistance values of 40 MΩ for resistors **1518** may serve as an alternative to the 4 photodiode per stream architecture of sensor **1502** described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor **1512** may provide enhanced performance because each of transimpedance amplifiers **1516** can be tuned or optimized to its respective photodiodes **1518**. In some embodiments, an averaging component **1520** may also be used to help cancel or reduce noise across photodiodes **1518**.

For purposes of illustration, FIG. **15**K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor **1522** may comprise a "4 PD per stream" architecture on a submount **700** in which each detector **106** comprises four (4) photodiodes **1524**. As shown for sensor **1522**, the output of each set of four photodiodes **1524** is then aggregated into a single transimpedance amplifier **1526** to produce a signal.

As another example, a sensor **1528** may comprise a "1 PD per stream" architecture on submount **700** in which each detector **106** comprises four (4) photodiodes **1530**. In sensor **1528**, each individual photodiode **1530** is coupled to a respective transimpedance amplifier **1532**. The output of the amplifiers **1532** may then be aggregated into averaging circuit **1520** to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor **1534** illustrates an exemplary "4 PD per stream" sensor in which the detectors **106** comprise photodiodes **1536** arranged in a linear fashion. Likewise, sensor **1538** illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes **1540** arranged in a linear fashion.

Alternatively, sensor **1542** illustrates an exemplary "4 PD per stream" sensor in which the detectors **106** comprise photodiodes **1544** arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor **1546** illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes **1548** also arranged in a zig-zag pattern.

FIG. **15**L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces **108** may be implemented using switched capacitor circuits and any number of front-end interfaces **108** may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface **1000** and signal processor **110**. Switched capacitor circuits may be useful in system **100** for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces **108** may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces **108** may require less computational power by signal processor **110** to perform the same amount of decimation to obtain the same SNR.

FIGS. **16**A and **16**B illustrate embodiments of disposable optical sensors **1600**. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors **1600** shown. For instance, the sensors **1600** can be used as the sensors **101** in the system **100** described above with respect to FIG. **1**. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors **1600** include an adult/pediatric sensor **1610** for finger placement and a disposable infant/neonate sensor **1602** configured for toe, foot or hand placement. Each sensor **1600** has a tape end **1610** and an opposite connector end **1620** electrically and mechanically interconnected via a flexible coupling **1630**. The tape end **1610** attaches an emitter and detector to a tissue site. Although not shown, the tape end **1610** can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates

a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling **1630** to the connector end **1620**. The connector end **1620** can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. **2**A through **2**D. Alternatively, the connector end **1620** can mate directly with the monitor.

FIG. **17** illustrates an exploded view of certain of the components of the sensor **301***f* described above. A heat sink **1751** and a cable **1781** attach to an emitter shell **1704**. The emitter shell attaches to a flap housing **1707**. The flap housing **1707** includes a receptacle **1709** to receive a cylindrical housing **1480/1580** (not shown) attached to an emitter submount **1702**, which is attached to a circuit board **1719**.

A spring **1787** attaches to a detector shell **1706** via pins **1783**, **1785**, which hold the emitter and detector shells **1704**, **1706** together. A support structure **1791** attaches to the detector shell **1706**, which provides support for a shielding enclosure **1790**. A noise shield **1713** attaches to the shielding enclosure **1790**. A detector submount **1700** is disposed inside the shielding enclosure **1790**. A finger bed **1710** provides a surface for placement of the patient's finger. Finger bed **1710** may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion **1705** may also be disposed in the finger bed **1710**. As shown, finger bed **1710** attaches to the noise shield **1703**. The noise shield **1703** may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield **1703** may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield **1703** may also comprise a thermistor **1712**. The thermistor **1712** may be helpful in measuring the temperature of a patient's finger. For example, the thermistor **1712** may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor **1712** may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover **1706** attaches to the pins **1783**, **1785**. Although not shown, a flex circuit can also be provided that connects the circuit board **1719** with the submount **1700** (or a circuit board to which the submount **1700** is connected). A flex circuit protector **1760** may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector **1760** may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector **1760** may be constructed from well known materials, such as a plastic or rubber materials.

FIG. **18** shows the results obtained by an exemplary sensor **101** of the present disclosure that was configured for measuring glucose. This sensor **101** was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor **101** were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. **19** shows the results obtained by an exemplary sensor **101** of the present disclosure that was configured for measuring glucose. This sensor **101** was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor **101** were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. **20** through **22** shows other results that can be obtained by an embodiment of system **100**. In FIG. **20**, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system **100** that comprised four LEDs and four independent detector streams. As shown, the system **100** obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. **21**, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system **100** that comprised four LEDs in emitter **104** and four independent detector streams from detectors **106**. As shown, the system **100** was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. **22** relate to total hemoglobin testing with an exemplary sensor **101** of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system **100** that comprised four LEDs in emitter **104** and four independent detector channels from detectors **106**. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

at least three light emitting diodes (LEDs);

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and

one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.

2. The user-worn device of claim 1, wherein glass covers each of the openings.

3. The user-worn device of claim 1 further comprising:

a network interface configured to wirelessly communicate the measurement of the physiological parameter to a mobile phone;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;

a memory configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

4. The user-worn device of claim 1 further comprising:

a network interface configured to wirelessly communicate the measurement of the physiological parameter to a computer network;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;

a memory configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

5. The user-worn device of claim 1 further comprising:

at least one wall extending between the interior surface and the protrusion, wherein at least the interior surface, the wall and the protrusion form one or more cavities, wherein the photodiodes are arranged within the cavities.

6. The user-worn device of claim 1, wherein the physiological parameter comprises oxygen or oxygen saturation.

7. The user-worn device of claim 1, wherein the physiological parameter comprises pulse rate.

8. The user-worn device of claim 1, wherein the physiological parameter comprises trending information.

9. The user-worn device of claim 1 further comprising:

a thermistor configured to output a temperature signal,

wherein the one or more processors are further configured to:

receive the temperature signal; and

adjust operation of the user-worn device responsive to the temperature signal.

10. The user-worn device of claim 9, wherein the temperature signal is responsive to a temperature of the tissue of the user.

11. The user-worn device of claim 1, wherein the LEDs and the photodiodes are arranged on a same side of the tissue of the user.

12. The user-worn device of claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.

13. The user-worn device of claim 1, wherein the one or more processors are further configured to process the one or more signals to determine a bulk measurement responsive to a positioning of the user-worn device.

14. The user-worn device of claim 1, wherein:

the at least three LEDs comprises at least six LEDs;

a first set of LEDs includes three of the six LEDs;

a second set of LEDs includes a different three of the six LEDs;

the second set is spaced apart from the first set;

a first of the three LEDs in the first set of LEDs is configured to emit light at a first wavelength and a second of the three LEDs in the first set of LEDs is configured to emit light at a second wavelength; and

a first of the three LEDs in the second set of LEDs is configured to emit light at the first wavelength and a second of the three LEDs in the second set of LEDs is configured to emit light at the second wavelength.

15. The user-worn device of claim 1, wherein the at least three photodiodes comprise four photodiodes arranged on the interior surface in a quadrant arrangement.

16. The user-worn device of claim 1, wherein the protrusion further comprises one or more extensions.

17. The user-worn device of claim 16, wherein the one or more extensions surround the convex surface.

18. The user-worn device of claim 1, wherein the protrusion further comprises one or more chamfered edges.

19. A user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least three photodiodes arranged within the user-worn device and configured to receive light attenuated by tissue of a user;

a protrusion extending over the three photodiodes and comprising a convex surface, the protrusion including a separate window associated with each of the three photodiodes, an opaque material lining a lateral surface of the windows and extending through the protrusion, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue; and

one or more processors configured to receive one or more signals from at least one of the photodiodes, the one or more processors configured to output measurements responsive to the one or more signals, the measurements indicative of a physiological parameter of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.

22. The user-worn device of claim 19, wherein the opaque material is configured to reduce an amount of noise caused by light piping in the one or more signals.

23. The user-worn device of claim 19 further comprising:

a network interface configured to wirelessly communicate the measurements to another computing device;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements; and

a memory configured to at least temporarily store at least the measurements.

24. The user-worn device of claim **19**, wherein the physiological parameter comprises an oxygen saturation or oxygen measurement.

25. The user-worn device of claim **19**, wherein the physiological parameter comprises a pulse rate.

26. A user-worn device configured to non-invasively measure a pulse rate of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged over the interior surface, the protrusion comprising a convex surface extending over the three photodiodes, the protrusion further comprising one or more sidewalls extending at least partially around a perimeter of the convex surface;

a plurality of openings extending through the protrusion and aligned with the three photodiodes, each opening defined by an opaque surface extending through the protrusion and configured to reduce light piping;

at least one wall extending between the interior surface and the protrusion, wherein at least the interior surface, the wall and the protrusion form one or more cavities, wherein the photodiodes are arranged within the cavities;

one or more processors configured to receive one or more signals from the photodiodes and calculate a pulse rate measurement of the user;

a user interface comprising a display, wherein the user interface is configured to display indicia responsive to the pulse rate measurement;

a memory configured to at least temporarily store at least the pulse rate measurement; and

a strap configured to position the user-worn device on the user.

27. The user-worn device of claim **26**, further comprising a network interface configured to wirelessly communicate the pulse rate measurement to a mobile phone.

28. The user-worn device of claim **26**, further comprising a network interface configured to wirelessly communicate the pulse rate measurement to a computer network without involving a mobile phone.

29. The user-worn device of claim **26**, wherein the protrusion further comprises one or more extensions.

30. The user-worn device of claim **26**, wherein the protrusion further comprises one or more chamfered edges.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 10,912,501 B2
APPLICATION NO. : 17/031356
DATED : February 9, 2021
INVENTOR(S) : Jeroen Poeze et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (63), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change "which is a division" to --which is a continuation--.

In the Specification

In Column 25 at Lines 10-18 (approx.), Change
"In certain embodiments, the focal length (f) for the partially

$$f = \frac{R}{n-1'}$$

cylindrical protrusion 605 can be expressed as:" to
--In certain embodiments, the focal length (f) for the partially cylindrical protrusion 605 can be expressed as:

$$f = \frac{R}{n-1'}$$

--.

Signed and Sealed this
Sixth Day of April, 2021

Drew Hirshfeld
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office